BIS VISTA™ Monitoring System

OPERATING MANUAL

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ABOUT THIS MANUAL

This Operating Manual contains all of the information you need to set up and operate the Aspect Medical Systems BIS VISTA™ Monitoring System. It also includes specific cleaning and test procedures you may occasionally be required to perform. Although this manual is intended for trained medical personnel, it does not assume prior knowledge or experience with operator-programmable medical electronics devices.

Keep this Operating Manual with the BIS VISTA monitor for use by the operator. This manual is also intended to be a service information manual for service technicians or biomedical engineering personnel.

Before attempting to set up or use the BIS VISTA system, please familiarize yourself with the safety information provided in this section.

INTRODUCING THE BIS VISTA MONITORING SYSTEM

Introduction

The BIS VISTA Monitoring System is a user-configurable patient monitoring system designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The BIS VISTA system processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS, which correlates with the patient's level of hypnosis.

The BIS VISTA monitor display consists of:

- The current BIS number
- Trend graphs of processed EEG parameters
- Raw EEG waveforms in real time
- Various signal quality indicators (EMG, SQI)
- Suppression Ratio (if requested by the user)
- Burst Count number (when a BIS Extend Sensor is in use)
- Alarm Indicator and Messages

The system performs self-tests to ensure that the monitor and its components are functioning properly and that impedance levels of patient sensors are within acceptable limits. Touch screen menus allow the user to change the data display and review stored data.

Important Information about Using BIS Monitoring

The BIS EEG VISTA Monitor System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The system, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS Index, one of the VISTA Monitor output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

BIS is a complex monitoring technology intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting BIS in conjunction with other available clinical signs. **Reliance on BIS alone for intraoperative anesthetic management is not recommended.** As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. BIS values should also be interpreted cautiously with certain anesthetic combinations, such as those relying primarily on either ketamine or nitrous oxide/narcotics to produce unconsciousness. Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders and those taking other psychoactive medications.

The BIS education site, www.biseducation.com, offers relevant information and published articles on the clinical use of BIS. In addition, there is a "Monitoring Consciousness Using the Bispectral Index during Anesthesia" Clinician's Pocket Guide available on the website and through your local Aspect Representative.

For more information, please contact Aspect Medical Systems at (800) 442-2051. If you require additional information on the use of BIS, please contact Aspect Medical Systems Clinical Support at 800-442-8655 or 617-559-7655 if calling from outside of the USA.

1 SAFETY PRECAUTIONS

INTRODUCTION

Caution:
Carefully read this entire manual before using the monitor in a clinical setting.

WARNINGS, CAUTIONS, AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A WARNING advises against certain actions or situations that could result in personal injury or death.
- A CAUTION advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.
- A NOTE provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols that may appear on the BIS VISTA system appears at the end of this section.

1.1 Warnings

EXPLOSION HAZARD: DO NOT USE THE BIS VISTA SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VISTA SYSTEM SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

DUE TO ELEVATED SURFACE TEMPERATURE, DO NOT PLACE BISx™ IN PROLONGED DIRECT CONTACT WITH PATIENT'S SKIN, AS IT MAY CAUSE DISCOMFORT.

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS DURING USE OF HIGH-FREQUENCY SURGICAL EQUIPMENT, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

TO REDUCE THE HAZARD OF BURNS DURING USE OF BRAIN-STIMULATING DEVICES (e.g., TRANSCRANIAL ELECTRICAL MOTOR EVOKED POTENTIAL), PLACE STIMULATING ELECTRODES AS FAR AS POSSIBLE FROM THE BIS SENSOR AND MAKE CERTAIN THAT SENSOR IS PLACED ACCORDING TO PACKAGE INSTRUCTIONS.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VISTA SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA), AS HAZARDOUS GASES MAY RESULT.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST GROUND LEAKAGE CURRENT BEFORE FURTHER USE.

LEAKAGE CURRENT MUST BE CHECKED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN WHENEVER INSTRUMENT CASE IS OPENED.

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VISTA POWER SUPPLY.

1.2 Cautions

Read this entire manual carefully before using the monitor in a clinical setting.

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Do not block ventilation inlet holes on the underside of monitor.

Do not open BISx for any reason. The seal to prevent liquids from entering the BISx may be damaged if opened.

Service or repairs must be performed only by qualified biomedical technicians.

The BIS VISTA system has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep™ technology and uses a proprietary connector. Use of other electrodes is not recommended.

To completely remove power from the unit: put the monitor in Standby mode, disconnect power cord from the power receptacle of the monitor, then remove the battery from the monitor.

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Considerations when using Electro-Convulsive Therapy (ECT) equipment during BIS monitoring: Place ECT electrodes as far as possible from the BIS sensor to minimize the effect of interference. Certain ECT equipment may interfere with the proper function of the BIS monitoring system. Check for compatibility of equipment during patient setup.

Check the battery periodically by operating a BIS VISTA monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage, charge the battery for 6 hours to assure full capacity. If the BIS VISTA monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VISTA monitor contains an internal Lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connector can interfere with PIC performance.

Service or repairs must be performed only by qualified biomedical technicians.

The BIS VISTA system complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications".

Do not disconnect the BISx during the software update.

When connecting or disconnecting BISx, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VISTA Monitoring System.

The BIS VISTA Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VISTA Monitor should be observed to verify normal operation in the configuration in which it will be used.

Important:
The BIS VISTA systems comply with the European Medical Device Directive (MDD) and applicable regulatory requirements of the country distributed to and carry the CE_{xxxx} Marking. Declarations of Conformity provided upon request where appropriate.

1.3 Key to Symbols

	Caution: Consult Accompanying Documents		Data I/O, RS-232 Serial Port
USB-A	Universal Serial Bus: Type A	**USB-B**	Universal Serial Bus: Type B
	Caution: Hot Surface		Storage Temperature Limits
	Type BF Equipment		Type BF Equipment Defibrillator-proof
	Alternating Current (A/C)		Direct Current (D/C)
	Battery Location		Reset Button
	Monitor Power ON		Monitor Power OFF or Standby Mode
	Do not Reuse		Use by YYYY-MM-DD or YYYY-MM
	Latex-free product		PVC-free product
	Manufacturer		Date of Manufacture
	Authorized Representative in the European Community		Catalog Number
	Batch Code		Serial Number
	Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CE_{xxxx} represents the Notified Body number		Classified by Underwriters Laboratories Inc.® with respect to electric shock, fire and mechanical hazards only, in accordance with UL 60601-1 and IEC60601-2-26
	Recognized under the Component Recognition Program of Underwriters Laboratories Inc.		Packaging Labeling: Fragile, Do Not Get Wet, and This Side Up

Figure 1 - Symbol Key (page 1 of 3)

	Recyclable		Crossed out wheelie bin indicates separate treatment from general waste at end of life *
	Product marked with a number contains certain toxic or hazardous substances or elements, and can be used safely during its Environment-Friendly Use Period (EFUP). The product should be recycled. The Environment-Friendly Use Period is valid only when the product is operated under the conditions defined in the product manual. **		Product marked with the "e" does not contain any toxic or hazardous substances or elements, and is green and environmental. The product can be recycled. **

*Contact Aspect Medical Systems International B.V. for a Return Materials Authorization (RMA) number. According to the WEEE Directive 2002/96/EC, all waste electrical and electronic equipment (EEE) should be disposed of and collected separately and treated according to the best available and environmentally friendly techniques.

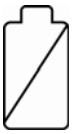
EEE contains hazardous substances to the (human) environment but also EEE is a valuable resource of new raw materials. Therefore it is important to collect WEEE separately from other waste.

Aspect Medical products are subject to the Directive and we therefore urge you to dispose of the equipment separately and make sure that it is treated at an electronics recycler. Please contact your municipality or the nearest collection site and dispose of waste equipment there and make sure the discarded equipment does not end-up in the 'normal' household waste.

** Refer to www.aspectmedical.com for Material Declaration Data Sheets.

Figure 1 - Symbol Key (Page 2 of 3)

Operating on Battery

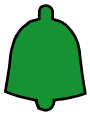


No Battery is Installed in Monitor

USB Drive: Data Export is in Progress

A Printable File Is Being Transferred to the USB Drive

Ringing Bell Icon - High Priority Alarm Sounding



Green Bell Icon - Alarms Active

Yellow Bell with Countdown Timer - Alarms Paused

Red Bell with 'X' - Alarms Silenced

A green box denotes ON or active condition.

A red box with an 'X' denotes OFF or cancel.

Figure 1 - Symbol Key (page 3 of 3)

2 INSTALLATION AND PREPARATION FOR USE

INTRODUCTION

This section provides installation instructions for the BIS VISTA Monitor, BISx, and accessories. It includes:

- Installation checklist
- Proper environment
- Required equipment and supplies
- Cable connections
- Start and shutdown procedures
- Initial menu settings

2.1 BIS VISTA Monitor Installation and Checkout

1. Open packages and inspect for all components:
   - Monitor (P/N 185-0151)
   - Power cord
   - Pole clamp
   - BISx (P/N 185-0145-AMS)
   - PIC (Patient interface cable, connects BISx to patient) (P/N 186-0107)

   Sensors are sold separately. For a list of available sensors please contact Aspect Medical Systems, Inc. or your local distributor.

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.
   - Verify that light to right of ON/Standby button is yellow.

3. Start up monitor by pressing the ON/Standby button (lower right corner).
   - Verify that light to right of ON/Standby button is green.
   - Verify all self-tests complete successfully.
   - Verify next screen says "Connect BISx."

4. Connect BISx with PIC to monitor.
   - Verify screen says, "BISx Initialization Complete."
   - Verify screen says "Connect sensor or cable."

5. Connect PIC and sensor.
   - Verify SENSOR CHECK begins.

6. Disconnect power cord from monitor.
   - Verify 'OPERATING ON BATTERY BACKUP' is displayed.

- Verify battery icon displays below BIS number.

7. Reconnect power cord.
   - Verify battery icon is not displayed below BIS banner.
   - Verify "OPERATING ON BATTERY BACKUP" is not displayed.

8. End of install.

2.2 Environment

2.2.1 Shipping and Storage Environment

The monitor and its accessories can be stored or shipped within the following environmental limits. Note that these limits apply to non-operational storage and shipping situations.

Temperature	-10°C to +60°C
Humidity	15% to 95% (non-condensing)
Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

Protect the monitor from sudden temperature changes that can lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

2.2.2 Operating Environment

The BIS VISTA Monitoring System is not designed for use in areas containing flammable gases or vapors.

WARNING:
EXPLOSION HAZARD: DO NOT USE THE BIS VISTA SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

The BIS VISTA monitor is designed to operate safely under the following conditions. Conditions outside these ranges could affect reliability.

Temperature	0°C to +40°C
Humidity	15% to 95% (non-condensing)
Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

2.2.3 Power Requirements and System Grounding

The BIS VISTA Monitoring System requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 0.7 ampere maximum.

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

WARNING:

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VISTA MONITOR SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

2.2.4 Electromagnetic Compatibility Requirements

The BIS VISTA Monitoring System should be used only with the power cord and accessories recommended and supplied by Aspect Medical Systems, Inc. The system must be installed and put into use according to the specifications described in Section 8.2 "Electromagnetic Compatibility Specifications."

Caution:

The BIS VISTA system complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications."

2.2.5 Site Preparation: Mounting the Monitor

Aspect Medical Systems, Inc. strongly recommends permanent mounting of the BIS VISTA monitor to the anesthesia machine to enhance safety and facilitate ease-of-use. Please contact your local representative or Aspect to discuss mounting options.

WARNING:
BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

2.2.5.1 Mounting the Monitor using the Pole Clamp

To mount the monitor to a secure vertical pole (1/2" - 1½" in diameter):

1. Place pole within clamp bracket and tighten screw using the black finger knob. Make sure that there is enough space above the clamp so that you have a few inches to slide the monitor in from above.
2. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp, and the monitor should snap securely into place.

Figure 2 - Pole Clamp

To remove the monitor, press tab on top of clamp shoe before sliding monitor up.

The pole clamp may be locked onto the monitor so that the two do not get separated. To do this:

1. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp and the monitor should snap securely into place.
2. Make sure that set screw hole on pole clamp aligns with corresponding hole on clamp shoe.
3. Remove black knob screw from pole clamp.
4. Using the Allen wrench supplied, secure pole clamp to monitor with the set screw provided.
5. Replace black knob screw.
6. To attach to pole, place pole within clamp bracket and tighten screw using the black finger knob.

2.2.5.2 Optional Mounting Accessories

For information on optional mounting accessories, request Aspect's "Monitor Mounting Solutions" booklet (part number 070-0031).

2.3 The BIS VISTA Monitoring System – Equipment and Supplies

The BIS VISTA Monitoring System consists of the following basic components:

- BIS VISTA Monitor (P/N 185-0151)
- BISx (P/N 185-0145-AMS)
- Patient Interface Cable (PIC) (P/N 186-0107)
- BIS Sensor
- Detachable Power Cord

Sensors are sold separately. For a list of available sensors please contact Aspect Medical Systems, Inc. or your local distributor.

A pole clamp is also included; however its use is optional. Contact Aspect or your local representative for information on additional equipment and accessories.

Figure 3 - The BIS VISTA Monitoring System

2.3.1 BIS VISTA Monitor

2.3.1.1 Front Panel

The front panel of the BIS VISTA monitor contains the Touch Screen, BISx port and the ON/Standby button. See Figure 3.

2.3.1.2 Touch Screen

The BIS VISTA monitor is designed so that all controls (with the exception of the ON/Standby button) are accessible by touching a designated area on the monitor screen. This area is called a touch key. The touch keys are designed to function even when the user is wearing examination gloves.

2.3.1.3 ON/Standby button

The ON/Standby button is located in the lower right corner of the monitor and indicates whether the monitor is ON or in Standby mode. When the small LED light to the right of the ON/Standby button is green, the unit is running and providing power to the BISx. When it is yellow, the battery is charging and the system is in Standby mode. When it is not lit, no A/C power is available to the unit; pressing the ON/Standby button will start up the monitor using the battery.

2.3.1.4 Rear Panel

The rear panel components are pictured in Figure 4. They include: two USB ports (Type A and B), the clamp shoe, an RS-232 port, the Reset button, the Battery/Power Supply cover, and the power cord receptacle.

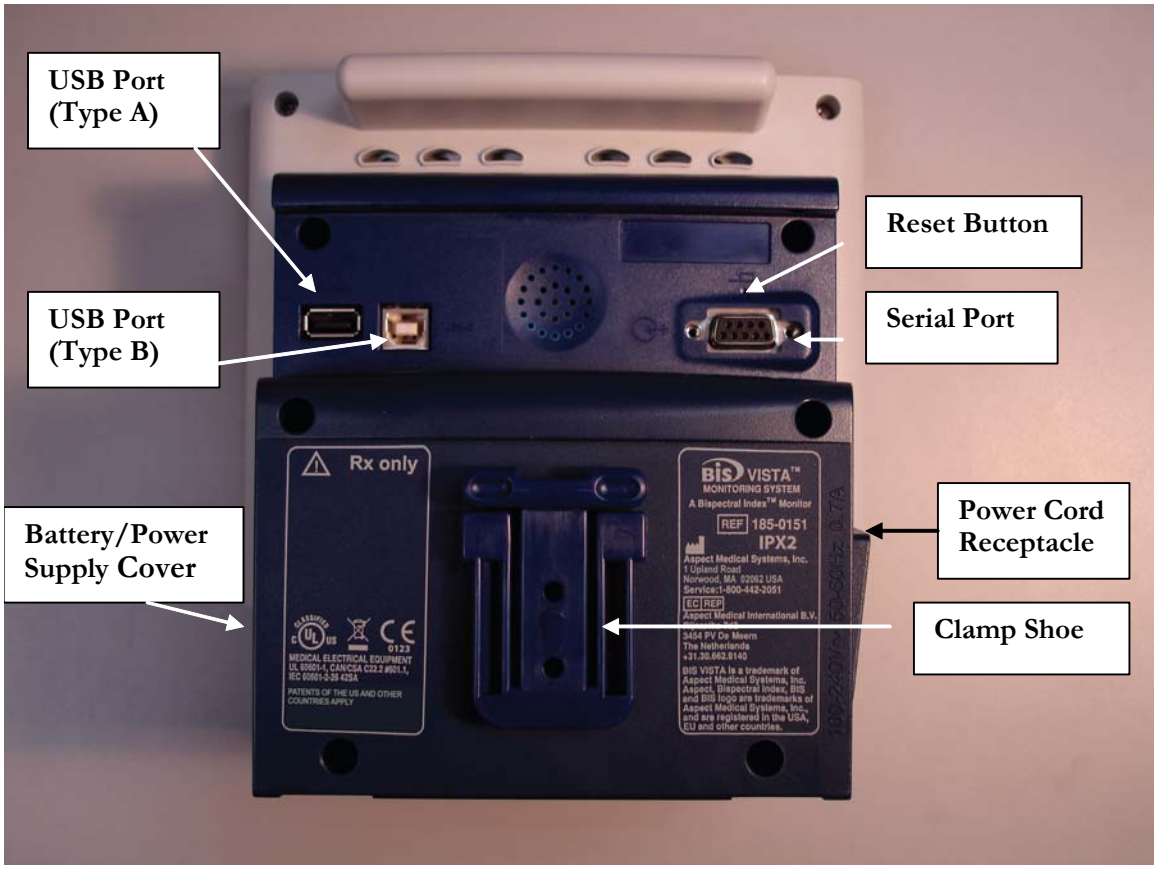


Figure 4 - Rear Panel

There are two **USB ports** on the rear of the monitor. The Type A port is used to export data to a removable drive. It is also used to update monitor and BISx software.

The **clamp shoe** allows the monitor to slide into the **pole clamp** so that it can be attached to a ½" – 1 ½" diameter vertical pole.

The **RS-232 serial port** can be used to transfer data from the monitor.

WARNING:
WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**

- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

Under normal operation, power is cycled through the ON/Standby button. The **Reset** button can be used to reset the software functions of the BIS monitor (and the BISx if it is attached) in the unlikely case that it is required. See Section 6.4. "Using the Reset Button."

The **Battery/Power Supply cover** contains the BIS VISTA monitor's power supply and allows access to its battery.

The **power cord receptacle**, located on the side of the Battery/Power Supply cover, is used to plug in the power cord provided by the manufacturer. It provides power to the monitor and to the BISx when it is attached.

Caution:

The BIS VISTA Monitoring System complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications".

2.3.1.5 Integral Battery

A rechargeable lithium ion battery inside the monitor provides approximately 45 minutes of back-up power when power cannot be supplied via the power cord. Recharge time is approximately 6 hours. The battery charges continually as long as the unit is plugged into A/C power.

When the system is running on battery, a battery icon displays indicating the battery status. A battery icon with four green bars indicates that the battery is fully charged. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color. In addition, a "Battery Voltage Low" message blinks in the Message area of the screen.

Caution:

Check the battery periodically by operating a BIS VISTA monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage, charge the battery for 6 hours to assure full capacity. If the BIS VISTA monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VISTA monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

2.3.2 BISx

Figure 5 - BISx and PIC

The BISx receives, filters, and processes patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment.

The BISx is shown in Figure 5. Its long flexible **Monitor Interface Cable** connects to the front of the monitor. The **Patient Interface Cable (PIC)** connects the BIS sensor to the BISx.

The attachment clip on the BISx is used to secure it in a convenient location near the patient's head.

WARNING:
DUE TO ELEVATED SURFACE TEMPERATURE, DO NOT PLACE BISx IN PROLONGED DIRECT CONTACT WITH PATIENT'S SKIN, AS IT MAY CAUSE DISCOMFORT.

Caution:
Do not open BISx for any reason. The seal to prevent liquids from entering the BISx may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

2.3.3 Patient Interface Cable (PIC)

Aspect's BIS Sensor Patient Interface Cable (PIC) (see Figure 3) connects the BISx to the BIS sensor.

2.3.4 BIS Sensors

The sensor is the single use component of the BIS Monitoring System and should be replaced after each use. For details on how to apply the sensor to the patient and how to connect to the BIS Monitoring System, refer to the BIS Sensor's instructions for use. All sensors, including the BIS Extend Sensor, utilize the monitor's saved settings (such as smoothing rate).

2.4 Cable Connections

After you have familiarized yourself with the safety information in the introductory section of this manual and have prepared a suitable environment, follow these steps to prepare the BIS VISTA system for operation.

1. **Connect the BISx to the monitor**
   Holding the cylindrical connector with the flat side up, plug the BISx Monitor Interface Cable into the BISx port on the front of the monitor.

   Once connected, the BISx need not be disconnected again. However, if you wish to disconnect the BISx cable from the monitor, carefully grasp the connector and pull. DO NOT pull on the cable.

2. **Connect the PIC to the BISx**
   Attach the gray connector of the Patient Interface Cable to the BISx.

Notes:

Connect with the BIS logo facing up for proper pin alignment. To disconnect the PIC, grasp the connector housing and pull firmly. DO NOT pull apart by the cable wire.

2.5 Start Procedure / Standby Mode

2.5.1 Starting the Monitor for the First Time

To start the instrument for the first time, after it has been reset with the RESET button, or after battery replacement:

1. Attach one end of the power cord to the receptacle on the left side of the monitor.
2. Plug the other end of the power cord into a properly grounded hospital-grade AC power outlet. A yellow light illuminates to the right of the ON/Standby button.
3. Press the ON/Standby button. The light changes to green and diagnostics tests run to verify that the system is operating properly. A beep indicates that the tests are complete. If there is a problem, the system halts and an error message appears. Error messages are explained in the Troubleshooting section of this manual.

When not in use, the monitor should be placed in Standby mode. To **put the system in Standby mode,** press and hold the ON/Standby button for two seconds before releasing. The light will change from green to yellow. If the monitor is running on battery, the light will go off completely.

2.5.2 Starting the Monitor from Standby Mode

When the monitor is in Standby mode (yellow light), you may start it by pressing the ON/Standby button. The light will change to green.

When not in use, the monitor should be placed in Standby mode. To **put the system in Standby mode,** press and hold the ON/Standby button for two seconds before releasing. The light will change from green to yellow. If the monitor is not connected to A/C power, the light will go off completely.

2.6 Initial Menu Settings

Before using the BIS VISTA monitor for the first time, you may need to select the proper language and set the current date and time. Other setting options are discussed in detail in Section 3.

The BIS VISTA monitor utilizes a touch screen. To access the Menus, press the [MENU] icon on the left side of the screen. Press the [Next] or [Previous] touch keys to scroll through the menu options. At any time you may press the [HOME] touch key to return to the main display screen.

2.6.1 Language Selection

The BIS VISTA monitor is designed to support multiple languages. If the screen does not display the desired language, follow these steps:

To change the language:

1. Press **[MENU].**
2. Press **[Next]** to go to the second menu, then **[Next]** again to go to the third menu.
3. Press **[Language]**. The current language is displayed.
4. Use the **[+]** or **[-]** keys to scroll through the list of languages until the desired language appears. All screens will now display in the selected language.
5. Press **[HOME]** to return to the main screen.

2.6.2 Date and Time

To set the current date and time:

1. Press **[MENU].**
2. Press **[Next]** to go to the second menu, then **[Next]** again to go to the third menu.
3. Press **[Date and Time].** A new screen displays the current date and time. "Day" is displayed in blue letters.
4. Use the up and down arrows to set the day of the month.
5. Press **[Month]**. "Month" is displayed in blue letters.
6. Use the up and down arrows to set the month.
7. Repeat this process for the "Year," "Hour," "Minute" and "Second" displays.
8. When you have finished, you may press [Return to Previous Menu] or press [**HOME]** to return to the main screen.

Note:

The time/date is initially set for the Eastern Standard or Eastern Daylight Time zone (USA). It will be necessary for you to change the time twice per year using the Time/Date feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

2.6.3 View/Save Settings

The BIS VISTA monitor will always start up configured to settings that have been saved in memory.

To save the current configuration settings,

1. Press **[MENU].**
2. Press **[View/Save Settings].** The current settings display.
3. Press **[Save Active].** The message, "Settings Saved" appears. The settings displayed will be saved except as noted below.
4. Press **[Previous]** or **[HOME]** to exit.

Notes:

The "Save Active" option is disabled when in Battery Backup-Low Power condition.

The following settings are not saved by the "Save Active" option: Impedance Checking (always returns to ON), Filters (returns to ON), and Display Type (returns to BIS).

Settings are set and saved for the current Monitor Mode only. See 3.5.10 "Monitor Mode."

See Section 3.5.6 "View/Save Settings" for instructions on restoring factory default values.

3 OPERATING THE BIS VISTA MONITORING SYSTEM

INTRODUCTION

This section covers:

- Preparing for operation
- The sensor check
- The monitor screen display
- Software menus and menu selections
- Reviewing stored data
- The EEG display
- Ending a case

Read this section before operating the monitor in a clinical setting.

3.1 Preparing for Operation

After you have familiarized yourself with the safety information in the introductory section of this manual, prepared a suitable environment, properly connected the BISx and PIC cables, and completed the initial settings described in Section 2, follow these steps to prepare the BIS VISTA Monitoring System for operation.

1. Startup and System Check
Press the ON/Standby button on the lower right corner of the monitor to start the monitor. The light changes from yellow to green, and the system initiates a self-test to make sure that all equipment is operating properly.

2. Attach BIS Sensor to Patient
Prepare sensor site and place the BIS sensor on the patient in accordance with the instructions included on the sensor packaging.

Caution:
The BIS VISTA Monitoring System has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.

WARNINGS!

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS DURING USE OF HIGH-FREQUENCY SURGICAL EQUIPMENT, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VISTA SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

3. Secure the BISx

Using the attachment clip, secure the BISx to a convenient location near the patient's head.

4. Attach the BIS Sensor to the PIC

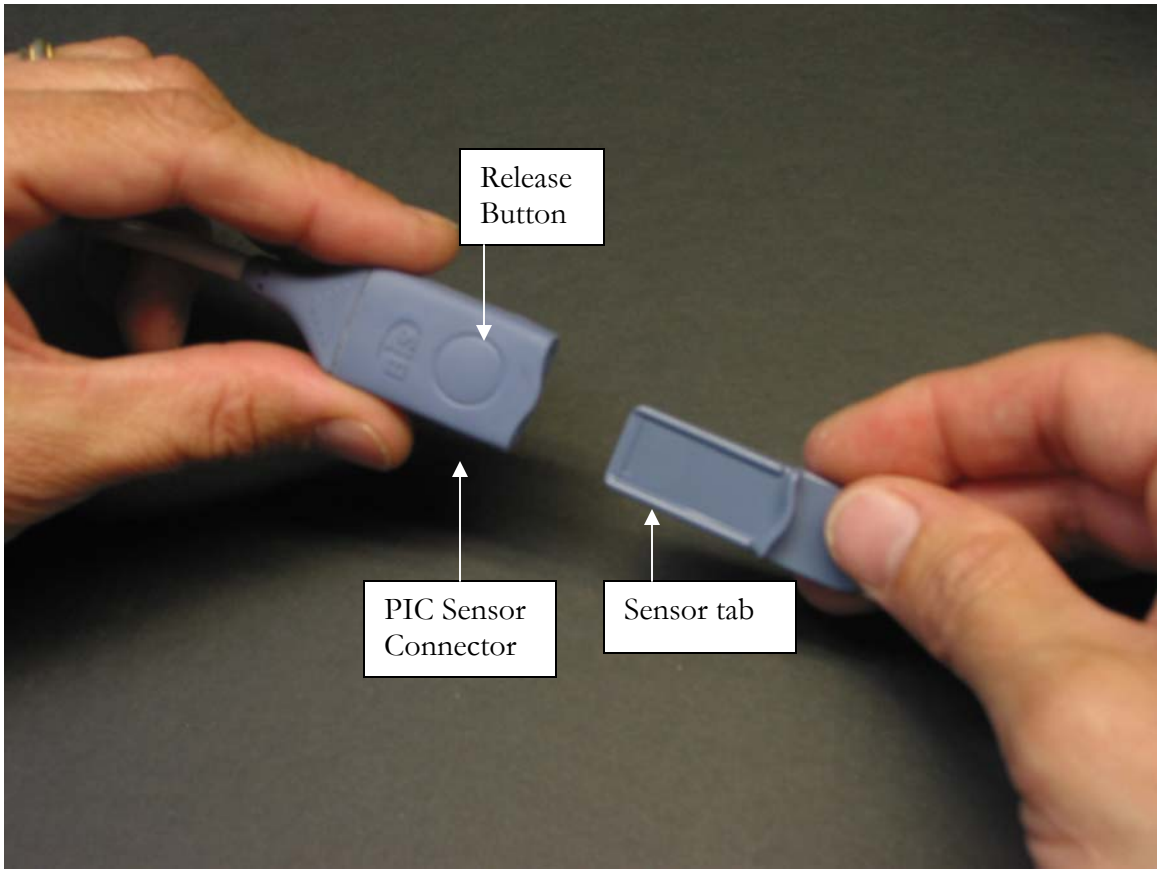


Figure 6 - Connecting the PIC

To insert the sensor into the PIC, line up as shown and insert the sensor tab into the PIC sensor connector until an audible "click" is heard. The blank side of the sensor tab (i.e. the side without the computer chip) should be facing up.

The Sensor Integrity Check is initiated each time that a sensor is connected to the PIC to make certain that a valid, unexpired sensor is in use.

3.2 Sensor Check

The Sensor Check tests the impedance of each electrode on the BIS sensor to verify that it is within an acceptable range for monitoring. A Sensor Check is initiated automatically when the sensor and PIC are connected to the BISx. It may also be initiated by the user by pressing the **[Sensor Check]** touch key.

The message, "Sensor Check in Progress" appears. When the sensor successfully passes the test, the Main Screen displays and monitoring begins.

If the sensor does not immediately pass the test, or if the user has manually initiated the test, the Sensor Check Graphic Screen displays. This screen shows the sensor with each electrode numbered. Colors indicate the status of each electrode:

- **Hollow circle** – No status is available. The electrode label will appear after a few seconds.
- **Green circle** with Checkmark – The electrode impedance is within the acceptable range. When all circles are green, monitoring can begin.
- **Red blinking circle** with 'X' – The electrode impedance is not within the acceptable range. Press the edges of the sensor to ensure adhesion and then press each circle for 5 seconds to ensure proper contact. Check all connections. If the problem persists, remove sensor, clean skin thoroughly, and reapply sensor or apply new sensor in accordance with instructions on the sensor packaging.
- **Gray circle** with Question Mark - The electrode impedance cannot be determined due to electrical interference (noise) from another source. Monitoring will not commence until the source of the noise has been removed and all electrodes have passed the sensor check.

If the user has requested the Sensor Check and all electrodes pass the test, the circles return to their original display color (blue) and the label, "PASS" displays at the bottom of the screen.

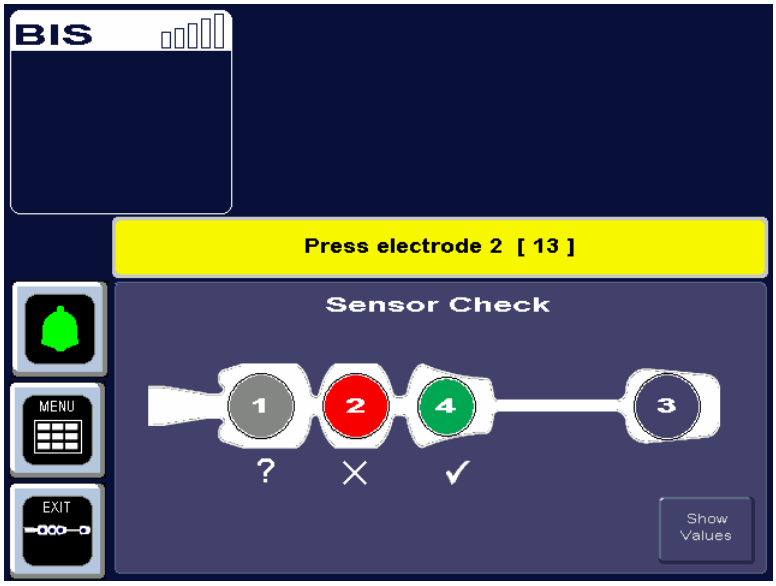


Figure 7 - Sensor Check Graphic Screen (Values not Shown)

If user action is required, messages in the message region of the screen issue instructions.

The monitor continues updating the values until all impedance values are acceptable. The **[EXIT]** touch key allows the user to exit the screen before the test has completed, however, the Sensor Check impedance test must be successfully completed before normal processing resumes.

For more detailed impedance information, press the **[Show Values]** touch key.

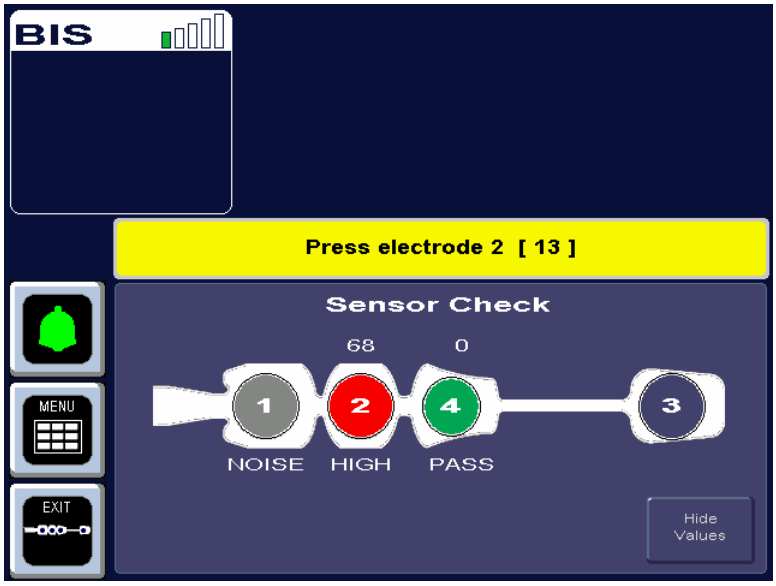


Figure 8 - Sensor Check Graphic Screen with Values Shown

In this display, the impedance value for each electrode, in kilo ohms, appears on the screen along with its status:

PASS - An electrode passes if the impedance for that electrode is less than 7.5 kilo ohms. The ground electrode (electrode #2) must be less than 30 kilo ohms to pass.

HIGH - An electrode is labeled "HIGH" if its impedance value is above 7.5 kilo ohms (30 kilo ohms for the ground electrode). As long as the combined impedance of electrodes #1 and #3 and the combined impedance of electrodes #1 and #4 are less than 15 kilo ohms, and the ground electrode is less than 30 kilo ohms, the sensor check will be considered successful.

NOISE - If the signal from the electrode goes beyond the measurable range, the label "NOISE" displays.

POOR CONTACT - If the impedance check indicates that the electrode is not in contact with the patient, the label "POOR CONTACT" displays.

To return to the previous display, press the **[Hide Values]** touch key.

To save this screen as the default screen, return to the menu system, press the **[View/Save Settings]** touch key, then press **[Save Active]**.

3.3 BIS Trend Data Screen

Once the sensor check has successfully completed, monitoring begins and the corresponding information appears on the screen.

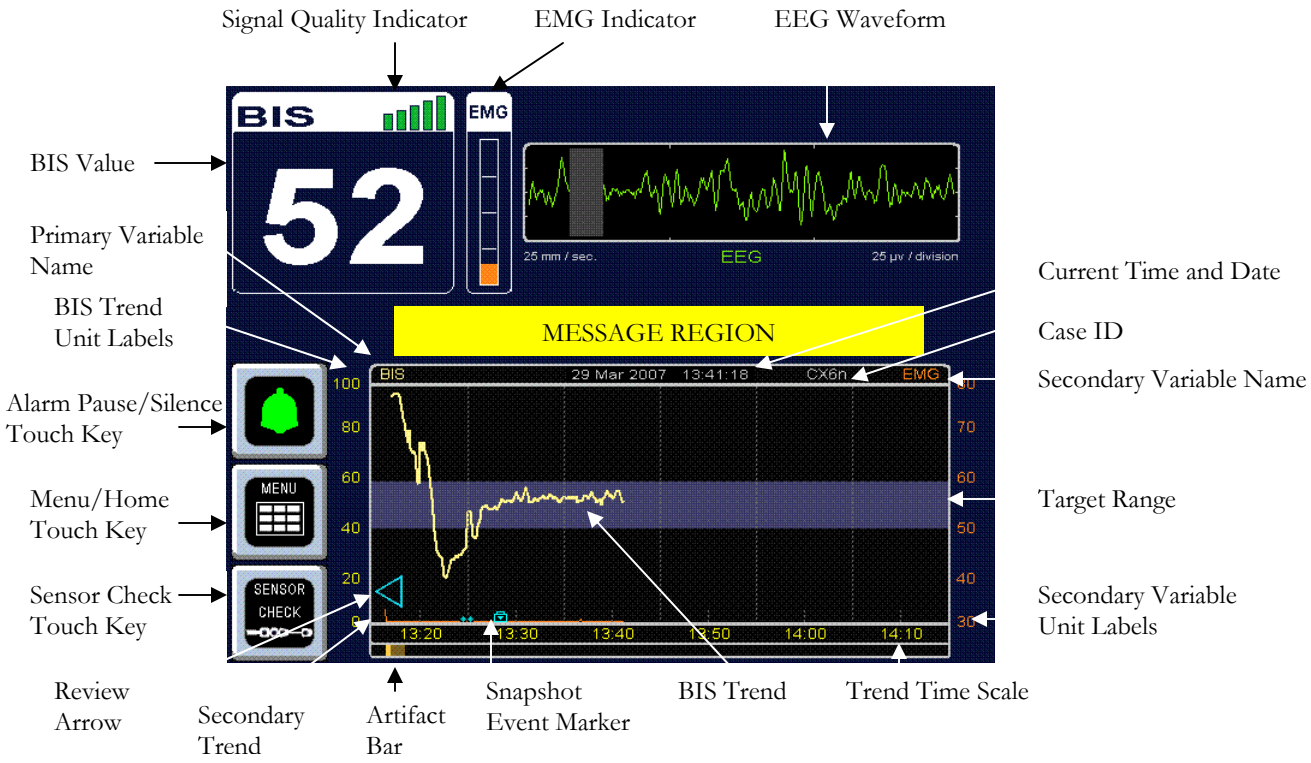


Figure 9 - Screen Features – BIS Trend Data Screen

3.3.1 BIS (Bispectral Index) Value

The current numeric value of the BIS is displayed in the upper left corner of the screen. The BIS number is displayed and continuously updated during all display modes as long as signal quality is sufficient.

3.3.2 Signal Quality Indicator

The Signal Quality Indicator (SQI) is a measure of the signal quality for the EEG channel source and is calculated based on impedance data, artifact, and other variables. It is displayed in the upper left corner of the screen, to the right of the "BIS" label. Signal quality is optimal when all five bars of the SQI icon are green. When signal quality is too low to accurately calculate a BIS value, the BIS value and other trend variables that are adversely affected by artifact will not be displayed on the screen.

3.3.3 Electromyograph (EMG) Indicator

The EMG bar graph displays the power (in decibels) in the frequency range 70 - 110 Hz. This frequency range contains power from muscle activity (i.e., electromyography or "EMG") as well as power from other high-frequency artifacts. When the indicator is low, it indicates that EMG activity is low. **BIS monitoring conditions are optimal when the bar is empty.**

1 bar represents power in the 30-38 range
2 bars represent power in the 39-47 range
3 bars represent power in the 48-55 range
4 bars represent power greater than 55.

3.3.4 EEG Waveform Display

Filtered electroencephalogram (EEG) waveforms are displayed above the BIS trend graph with a sweep rate of 25 millimeters per second and a scale of 25 microvolts (1 channel) or 50 microvolts (2 channels) per division. One or two channels of EEG may be displayed in this area. EEG filters can be turned off, if desired.

An alternate screen display is available to view the waveforms in a larger format. Refer to Section 3.7 "EEG Display" for information.

3.3.5 Message Region

The Message Region is a space reserved for status and error messages. These messages are prioritized so that a high priority message displays before a lower priority message. The background color of the message indicates its priority:

Message Priority	Background Color
High	Orange
Medium	Yellow
Low	Grey
Information only	Dark Blue

Diagnostic codes may be displayed above the messages by activating them in the Diagnostic Menu. Specific error messages are explained in the Troubleshooting section of this manual (Section 6).

3.3.6 BIS Trend Graph

The BIS Trend Graph plots the values of the Bispectral Index over time. The **BIS trend** is indicated with a thick line and its unit labels appear on the left axis. The name BIS is displayed above the left corner of the graph and the current date and time display in the center. (See Figure 9 and Figure 10.)

On the right, a unique **Case ID number** is displayed. A new case number is assigned when a new sensor is attached to the PIC and passes the Sensor Check.

If a **target range** for BIS has been set, the target area displays as either a colored bar or two horizontal lines showing the upper and lower target ranges (depending on the user setting). If the BIS value falls outside of the target range, a message displays in the Message Region of the screen, and if an audible alarm was requested in the target range setup screen, the alarm sounds (unless alarms have been silenced). The alarm continues to sound until the BIS value returns to the target range or the alarm is silenced by pressing the alarm touch key. See Section 3.5.1 for more information.

A **secondary variable** may be added to the display by selecting "Suppression Ratio," "EMG," "Signal Quality" or " Bursts/Minute" as a secondary variable in the menu system. (See Section 3.5.2 "Secondary Variable" for instructions.) The secondary trend is shown with a thin line and its unit labels appear on the right axis. The secondary trend name is displayed above the right corner of the graph. Note that Burst Count is only available as a secondary variable when a BIS Extend Sensor is in use.

During periods of poor signal quality, an **artifact bar** appears along the horizontal axis at the bottom of the graph. When signal quality is considered too low to calculate a BIS value, the bar becomes bright yellow and any trend variables that are adversely affected by artifact will not be displayed.

A **Data Snapshot** may be taken to save up to 10 minutes of data leading up to a significant event. A **Data Snapshot Marker** (a camera icon) displays at the bottom of the BIS Trend Graph at the time the snapshot was taken. Only one set of data is saved in memory at a time. When a second snapshot is taken, the snapshot marker from the first snapshot changes from a camera to a diamond and its data are overwritten. Snapshot data may be saved to a removable drive. To export snapshot data, see Section 3.5.11 "Export Data." To save snapshot data in a printable (PDF) format, see Section 3.5.13 "Print (Snapshot)."

If desired, EEG may be displayed in place of the BIS Trend Graph by selecting the EEG display mode in the menu system. See section 3.5.5 "BIS/EEG Display Modes" for details. During the sensor check procedure, this area of the screen is used to issue instructions and report current status.

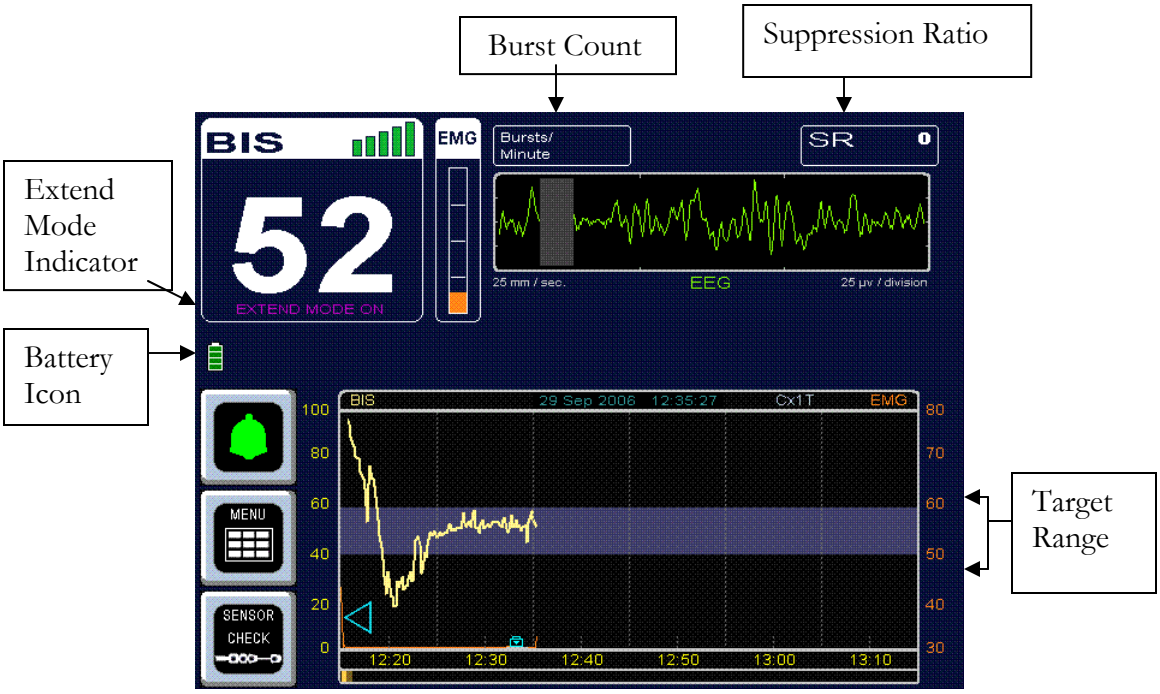
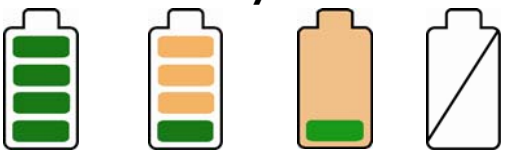


Figure 10 - BIS Trend Data Screen with Battery Icon, Target Range, SR, and Burst Count

3.3.7 Additional Screen Information

3.3.7.1 Battery Icon



The battery icon is displayed below the BIS number when the monitor and BISx are running on battery power. When the battery icon contains four green bars, the battery is fully charged. When the icon turns orange, the battery is nearly depleted.

If an empty battery icon displays on the screen with a slash across it, there is no battery in the monitor.

3.3.7.2 USB Export Icon

The USB Export icon is displayed below the BIS number during data export to a removable USB drive inserted in the rear of the monitor.

3.3.7.3 Print Icon

The Print icon is displayed below the BIS number while printable files are being written to a removable USB drive inserted in the rear of the monitor.

3.3.7.4 Extend Mode

The message, "EXTEND MODE ON," displays below the BIS number when a BIS Extend Sensor is in use. Note that the monitor automatically changes to the smoothing rate that was set in Mode II (ICU) when a BIS Extend Sensor is attached.

3.3.7.5 Suppression Ratio (SR) Number

The Suppression Ratio (SR) is displayed in the upper right corner of the screen only when it has been requested by the user. Suppression ratio is a calculated parameter designed to indicate when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state. For example: SR=11 (isoelectric over 11% of the last 63 second review).

When SR reaches 100%, the message "Isoelectric EEG Detected" will notify the user. Suppression ratio can be plotted over time as a secondary trend on the BIS Trend Graph.

3.3.7.6 Burst Count (Bursts/Minute)

When a BIS Extend Sensor is in use, the Burst Count is displayed above the EEG waveform display. Burst Count is an alternative method of quantifying suppression, reported as the number of EEG bursts per minute. The system defines a "burst" as a short period of EEG activity, preceded and followed by periods of inactivity. When the signal quality is low or when the Suppression Ratio is less than 5, the Burst Count is not displayed.

The Burst Count may also be graphed as a secondary variable on the BIS Trend Graph.

3.4 Main Screen Touch Keys

3.4.1 Alarm Touch Keys

Alarms sound to alert the user to possible problems with the patient or the equipment. Alarm conditions are prioritized so that high priority alarms take precedence over lower priority alarms. The user may silence the currently sounding alarm or silence all alarms. Alarm volume may be set in the menu system.

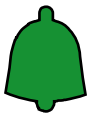
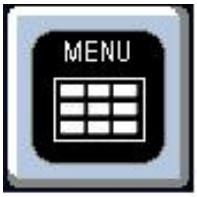
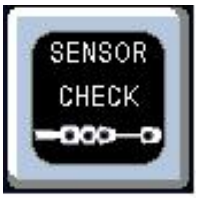
Alarm Sounding	When a high priority alarm is sounding, the ringing bell displays. Pressing this icon silences the current alarm, but does not prevent other alarms from sounding if another priority alarm condition should occur. Alarm messages continue to display in the message area as long as the alarm condition exists.
 Alarms Active	A green bell icon indicates that the alarms are active and will sound if activated. Pressing this icon changes the alarm status to "Alarms Paused" and the yellow bell icon displays.
Alarms Paused	A yellow bell indicates that all alarms have been silenced for two minutes. A countdown timer counts down the seconds until the alarm sounds again. Pressing this icon changes the alarm status to "Alarms Silenced" and the red bell icon displays.
Alarms Silenced	The red bell with a solid "X" over it indicates that all alarms have been silenced indefinitely. Pressing this icon restores the active alarms and the green bell icon displays.

Figure 11 - Alarm Touch Keys

3.4.2 Menu, Home, Sensor Check and Review Touch Keys

	**The MENU/HOME touch key:** The **[MENU]** touch key is used to enter the Menu system.
	When a menu displays, the **[MENU]** touch key becomes the **[HOME]** touch key. The **[HOME]** touch key is used to return to the main display screen.

	**The SENSOR CHECK touch key:** This touch key is used to begin a sensor impedance check. Sensor Check is initiated automatically when the PIC and sensor are attached to the BISx. You may initiate another check at any time by selecting this option. When an automatic check has been completed successfully, the screen will exit automatically. Otherwise, the user may press the **[EXIT]** key at any time to exit. For details on the sensor check procedure, refer to Section 3.2 "Sensor Check."

	The Review Mode Arrow This touch key is used to enter Review Mode

Figure 12 - Menu, Home, Sensor Check and Review Mode Touch Keys

3.5 Menu Selections

Before using the BIS VISTA monitor for the first time, you may want to update the monitor with your desired screen settings and the current date and time. You should also familiarize yourself with the various menu options available. This section describes the menu options available and how they work. These menu options are discussed below. For more detail on what the settings mean, refer to "BIS Trend Data Screen" in Section 3.3.

3.5.1 Target Range

To access the Target Range, press **[MENU].**

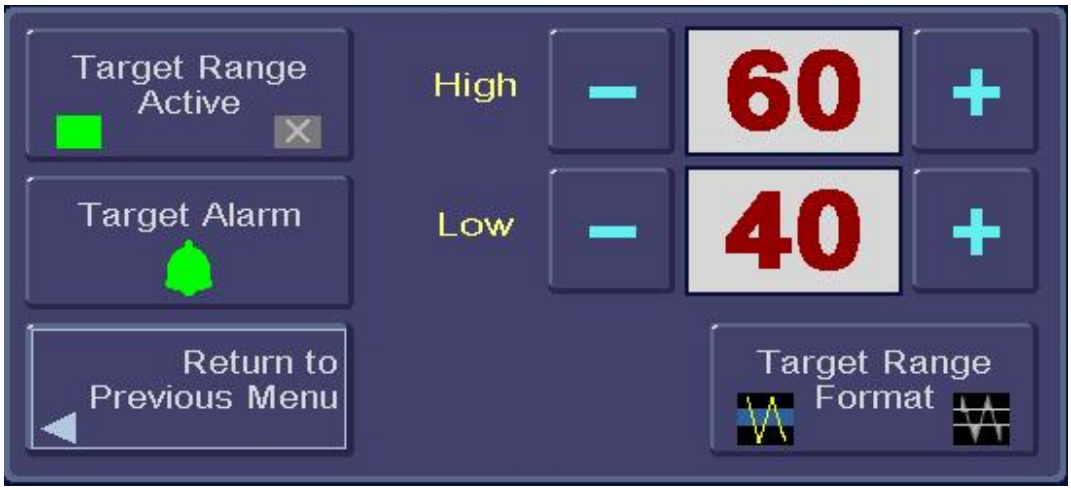


Figure 13 - Target Range

To aid in patient management, a target range of desired BIS values may be set. When the Target Range is activated, the selected range displays on the BIS Trend Graph. The BIS VISTA monitor will notify the user when the patient's BIS value is outside of the intended range. The Target Range menu has four components:

1. Activating the Target Range feature so that the range displays on the BIS Trend Graph.
2. Setting the Target Range display format (colored band or two horizontal lines).
3. Setting the audible alarm to sound when a BIS value falls outside of the range.
4. Setting a Target Range of desired BIS values.

To set the Target Range options, press **[Target Range]**. The Target Range Screen displays.

1. To activate the Target Range so that it displays on the BIS Trend Graph, or deactivate it so that it does not, press **[Target Range Active]**.
   - When the Target Range is active, a green box displays.
   - When the Target Range is inactive, a red box with an 'X' displays.

2. To change the Target Range display format, press the **[Target Range Format]** touch key. When the left side of the **[Target Range Format]** key is illuminated, the Target Range will display as a colored band. When the right side of the **[Target Range Format]** touch key is illuminated, the Target Range displays as a pair of horizontal lines denoting the upper and lower limits.
3. To activate or deactivate the target alarm, press **[Target Alarm]**.
   - A green bell indicates that the Target Alarm is active. Alarms will sound when the BIS value falls outside of the Target Range, unless the alarms have been silenced on the main screen.
   - A red bell with an 'X' indicates that the Target Alarm is inactive. Audible Target Alarms will not sound.
4. The Target Range upper (High) and lower (Low) limits are displayed between minus and plus signs. To change the Target Range, use the [+] and [-] touch keys to increase or decrease the Target Range limits. Each key press will change the limit by a factor of 5. The system will not allow the difference between the upper and lower limits to be less than 5. A high value of 100 = none, and a low of 0 = none.

To permanently save this change, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.2 Secondary Variable

To access **Secondary Variable**, press **[MENU].**

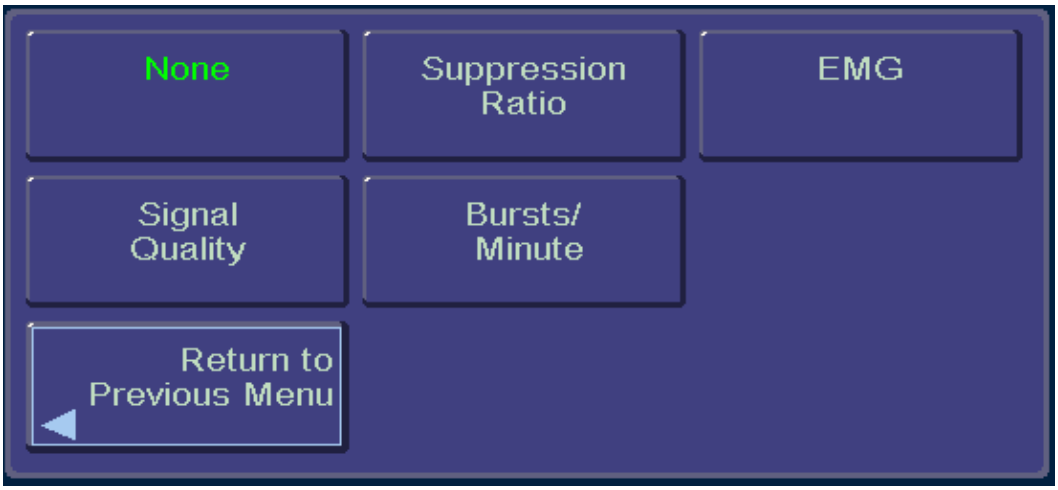


Figure 14 - Secondary Variable

This option allows the user to add a secondary trend variable to the Trend Graph:

- Selecting "**Suppression Ratio"** will plot the suppression ratio.
- Selecting "**EMG**" will plot electromyograph or high frequency signal detection.
- Selecting "**Signal Quality**" will plot a number (0 – 100) that indicates the quality of the EEG signal received and processed.
- Selecting "**Bursts/Minute**" will plot the burst count in number of bursts per minute. Note that this is available only when a BIS Extend Sensor is attached to the PIC. If a BIS Extend Sensor is not connected, this menu option does not appear.
- Selecting "**None**" removes the secondary variable from the graph.

To specify a secondary variable:

1. Press **[MENU]** to access menu options.
2. The **[Secondary Variable]** touch key displays the options available. The current setting displays in green.
3. Press the desired touch key (Suppression Ratio, EMG, Signal Quality, Bursts/Minute, or None).
4. When the desired setting is displayed in green letters, press **[Return to Previous Menu]** or **[HOME]** to exit.

To permanently save this change, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.3 Chart Data

To access **Chart Data** press **[MENU].**

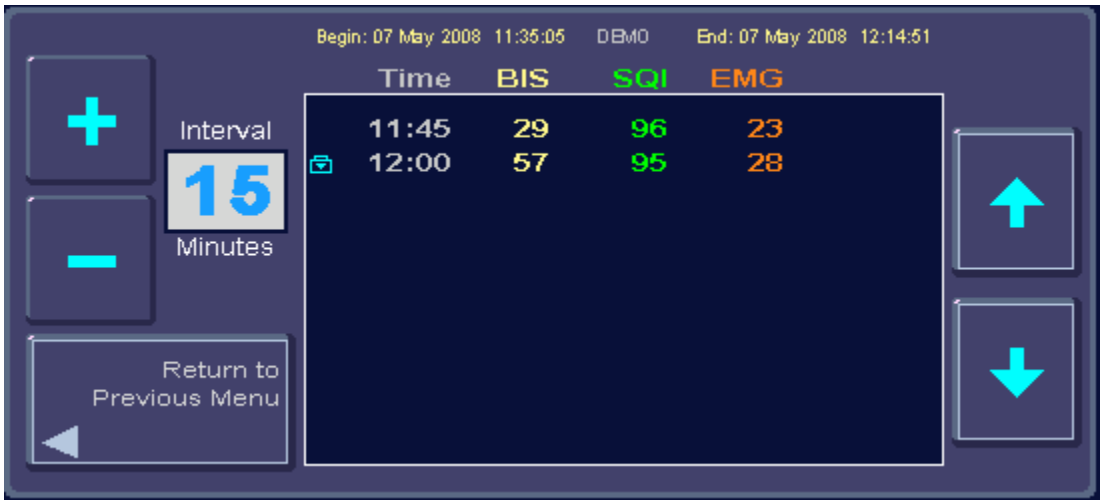


Figure 15 - Chart Data

When selected, this option provides a listing of BIS, SQI and EMG values at a selected interval, so that they can be recorded on the patient chart. The charting interval can be changed by the user. Available intervals are 1, 5, 10, 15, 30, and 60 minutes. If a data snapshot was taken during the case, the snapshot icon appears on the chart at the corresponding time.

To chart data:

1. Press **[MENU]** to enter the menu system.
2. Press the **[Chart Data]** touch key. The Chart display appears.
3. To change the charting interval, use the **[+]** and **[-]** touch keys. Available intervals are 1, 5, 10, 15, 30 and 60 minutes.
4. Use the **[↑]** and **[↓]** arrows to scroll through the data.
5. Press **[Return to Previous Menu]** or **[HOME]** to exit.

3.5.4 Alarm Volume

To access **Alarm Volume**, press **[MENU].**

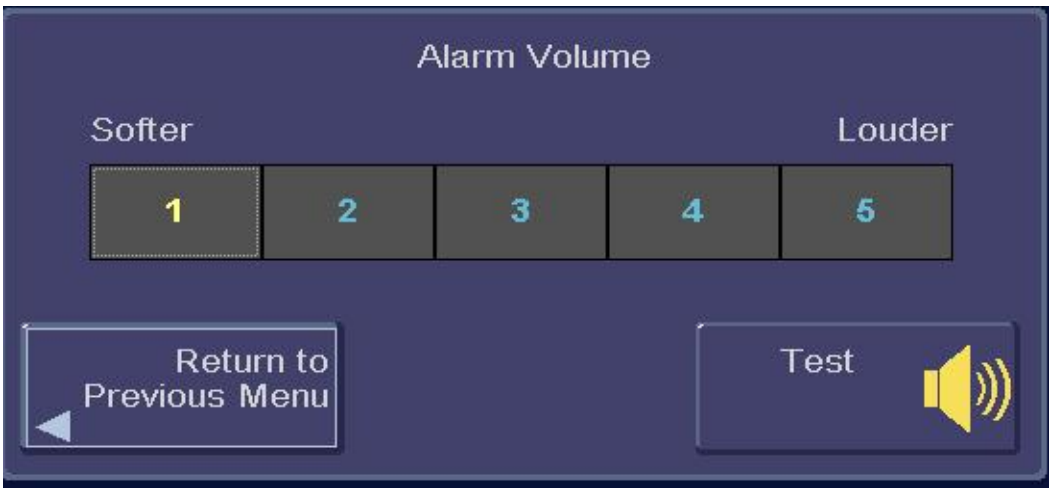


Figure 16 - Alarm Volume

The alarm volume can be set within a range, from low to high. The user may listen to the loudness of the current alarm by pressing the "Test" button.

To change the Alarm Volume:

1. Press **[Alarm Volume]**. The Alarm Volume screen appears.
2. Press a number from 1-5 on the touch screen to select the desired volume.
3. Press and hold the "Test" key to listen to the alarm volume you have set.
4. When the volume is set to the desired level, press **[Return to Previous Menu]** or press **[HOME]** to exit.

To permanently save this change, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.5 BIS/EEG Display Modes

To access **BIS/EEG** Display Modes, press the **[MENU]** touch key**.**

Figure 17 - BIS/EEG Display Modes

The main display area of the BIS VISTA monitor can display either BIS Trend Graph or the EEG. (Refer to Section 3.7 "EEG Display" for more information.) The **[BIS/EEG]** touch key displays the current display mode (BIS or EEG) in green letters. To change the display, press the **[BIS/EEG]** key to toggle back and forth between the two display modes until the desired mode appears in green letters.
Press **[HOME]** to exit.

The system defaults to the BIS Trend Data Screen display.

3.5.6 View/Save Settings

To access the **View/Save Settings** function**,** press **[MENU].**

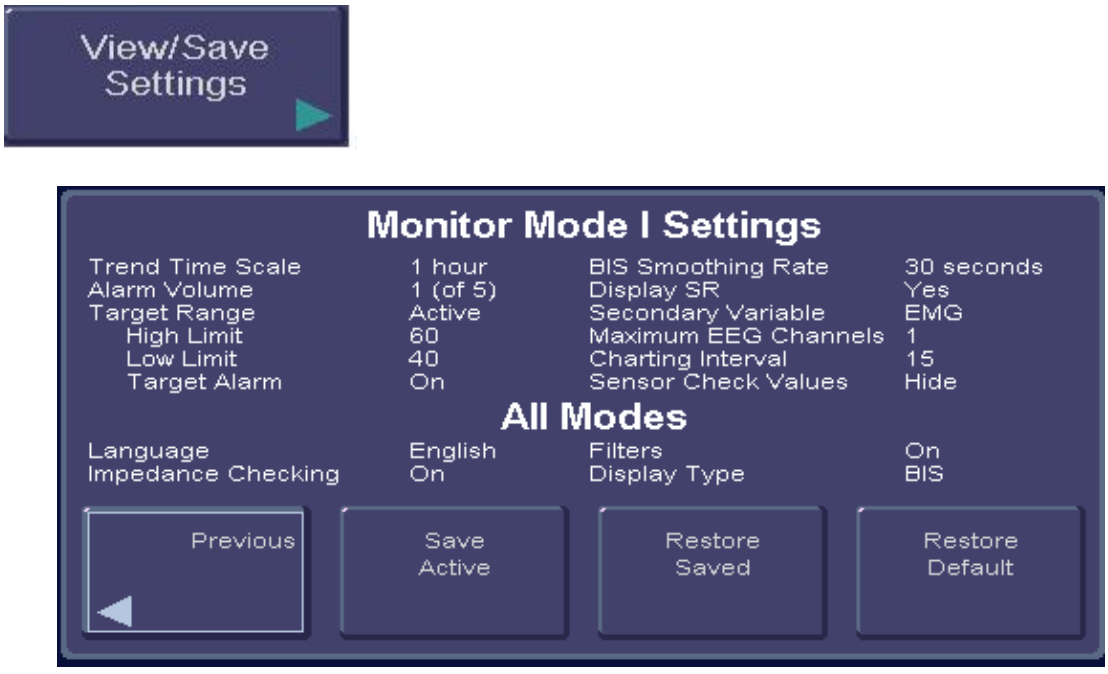


Figure 18 - View/Save Settings

Whenever the monitor is started up from Standby mode, it reverts to user settings that have been set up and then saved using the **[Save Active]** touch key on the **View/Save Settings** screen. Settings are saved to the current Monitor Mode (I, II, III, or IV).

To **view or save** the current configuration settings, press **[View/Save Settings]**. The current settings display on the screen. Settings that are active but have not been saved are displayed in yellow.

Save Active: Press this touch key to save the settings on display (the "Active" Settings) to the current Monitor Mode. The message, "Settings Saved" appears. The settings displayed will be saved except as noted below:

Notes:

The "Save Active" option is disabled when in Battery Backup-Low Power condition.

The following settings are not saved by the "Save Active" option: Impedance Checking (always returns to ON), Filters (returns to ON), and Display Type (returns to BIS).

Settings are set and saved for the current Monitor Mode only (See 3.5.10 "Monitor Mode").

Restore Saved: Press this touch key to return the current settings to the previously saved settings (the start-up settings). This applies to the current Monitor Mode only.

Restore Default: Press this touch key to restore the factory default settings. This applies to the current Monitor Mode only. This restores the default values until the next time the monitor is re-started. To permanently restore the default settings, press **[Restore Default]** and then press **[Save Active]**.

To restore the factory settings to all Monitor Modes, go to the Maintenance Menu and press **[Restore Default Settings for All Modes]**.

Press **[Previous]** or **[HOME]** to exit.

3.5.7 Help

To access **Help**, press **[MENU]**.

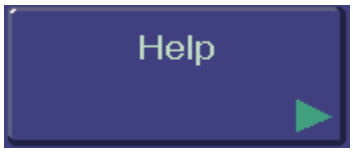


Figure 19 - Help

The **[Help]** touch key allows the user access to information on use of the BIS VISTA Monitoring System including: sensor placement, BIS guidelines, troubleshooting and system features. Press the **[Help]** key, then follow the on-screen instructions.

3.5.8 Snapshot

To access the **Snapshot** function, press **[MENU].**

Figure 20 - Snapshot

This option is used during operation to mark a significant event on the trend screen display and to save the previous 10 minutes of data leading up to the event. Snapshot data is saved in memory until another snapshot is taken.

To take a data **Snapshot,** press **[Snapshot]**. The event is immediately marked with a snapshot marker (a camera icon) on the time scale of the BIS Trend Graph. If a snapshot is already in memory, the message "Warning: Snapshot in memory will be erased. Press 'Save Snapshot' button to save new snapshot" notifies the user. If the new snapshot is saved, the previous snapshot marker displayed on the time scale changes to a diamond, and the new snapshot marker displays as the camera icon.

Snapshot data may be sent to a removable drive. To export snapshot data, see Section 3.5.11 "Export Data." For snapshot data in a printable (PDF) format, see Section 3.5.13 "Print (Snapshot)."

3.5.9 Display Suppression Ratio (SR)

To access **Display SR**:

1. Press **[MENU]**.
2. Press **[Next].**

Figure 21 - Display SR

The user may choose whether or not to display the Suppression Ratio (SR) on the main screen.

To change the setting, press **[Display SR]**.

- When the key shows a green box, the Suppression Ratio will display on the main screen.
- When the key shows a red box with an 'X', the Suppression Ratio will not be displayed.

To permanently save this change for the current Monitor Mode, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.10 Monitor Mode

To access **Monitor Mode**:

1. Press **[MENU].**
2. Press **[Next].**

The BIS VISTA monitor has four preset configurations (I, II, III, and IV) for use in different types of cases. Each mode has its own settings, which are set up during installation.

The default settings for each mode are shown in Figure 22, "Monitor Mode Settings."

Variable	Default Value			
	I	II	III	IV
Trend Time Scale (hours)	1	1	1	1
Alarm Volume	1	1	1	1
Target Range	Inactive	Inactive	Inactive	Inactive
Target Alarms Audible	On	On	On	On
Target Range Display Format	Color Bar	Color Bar	Color Bar	Color Bar
BIS Smoothing Rate	15	30	10	15
Display SR on Main Screen	No	Yes	No	No
Secondary Variable	EMG	EMG	EMG	EMG
Maximum Number of EEG Channels	1	1	1	4*
Charting Interval	15 minutes	15 Minutes	15 Minutes	15 Minutes
Sensor Check Values	Hide	Hide	Hide	Hide

*Only two channels display unless a BIS Bilateral Sensor and BISx4 are in use.

Figure 22 - Monitor Mode Settings

Settings may be changed for the current mode. When the settings are saved using the "View/Save Settings" function, they are saved for the current mode only.

Factory settings for the current mode may be restored using the "View/Save Settings" function. To restore factory settings for all modes, use "Restore Default Settings for All Modes" in the Maintenance Menu.

To change the monitor mode:

1. Press **[MENU]** to access menu options.
2. Press **[Monitor Mode]**.
3. Press the desired Mode.
4. Press **[Return to Previous Menu]** or press **[HOME]** to exit.

To permanently keep the monitor in the new mode, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.11 Export Data

To access the **Export Data** function:

1. Press **[MENU]**.
2. Press **[Next]**.

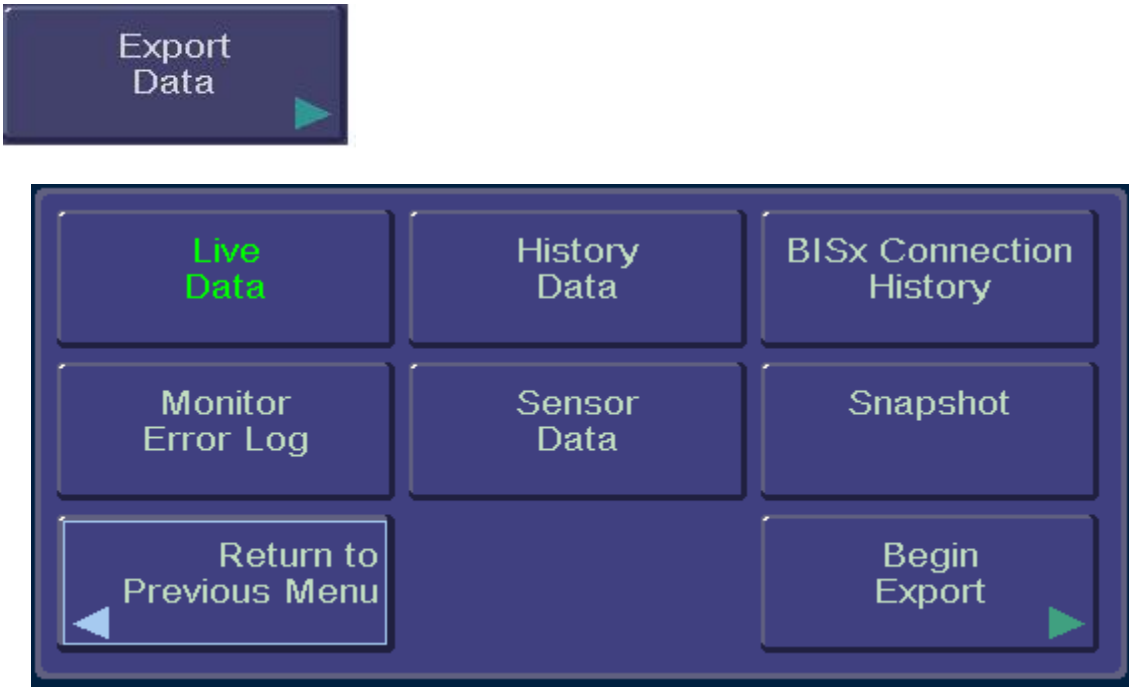


Figure 23 - Export Data

- This selection allows the user to send data to a removable drive via the USB port (Type A) at the rear of the monitor, or to a device connected to the monitor's serial port. For a list of acceptable USB drives, please contact Aspect Medical Systems Technical Service. (Contact information is listed on the back cover of this manual.)

The various types of data that may be exported are listed below.

- **Live Data**: When this option is selected, live case data (BIS values, SQI, EMG and unfiltered EEG waveforms) are exported. Live data files are named using the format LMMDDHHMM, where 'L' stands for Live Data, MM is the two-digit month, DD the two-digit day, HH is the two-digit hour and MM the two-digit minute that the data were exported.
- **History Data**: When this option is selected, case data stored in the BISx are exported. BIS values, SQI and EMG are reported at one-minute intervals. History data files are named using the format HMMDDHHMM, where the initial 'H' stands for History data, followed by the two-digit month, day, hour, and minute that the data were exported.
- **BISx Connection History**: This option reports which BISx units were connected to the monitor. The BISx serial number and the date and time of each connect and disconnect are noted. Files are named using the format nx_bisxcDDMMYYYYHHMMSS_SN*xxxxxxx*.log, where 'nx_bisxc' stands for BISx Connection, followed by the two-digit day and month, four-digit year, and two-digit hour, minute, and second that the data file was created and *xxxxxxx* is the monitor serial number.
- **Monitor Error Log**: This option reports all system errors, including those related to the monitor, BISx, PIC or sensor. Files are named using the format nx_errorDDMMYYYYHHMMSS_SN*xxxxxxx*.log, where 'nx_error' indicates that it is an error log, followed by the two-digit day and month, four-digit year, and two-digit hour, minute, and second that the data file was created, and *xxxxxxx* is the monitor serial number.
- **Sensor Data**: This option lists sensor information stored in the BISx. Files are named using the format SDMMDDHHMM where 'SD' indicates Sensor Data, followed by the two-digit month, day, hour and minute that the data were exported.
- **Snapshot**: This option sends the most recent snapshot data. Files are named using the format SMMDDHHMM where 'S' stands for Snapshot, followed by the two-digit month, day, hour and minute that the data were exported.

Information on the data file format may be obtained by contacting Aspect Technical Service. (See back cover for contact information.)

BIS is not processed during History Data or Sensor Data Exports. For all other exports, when a case is in process, the BIS number will continue to update and display during the export process.

In order to export data, the system must be powered ON and the BISx must be connected to the monitor. If the removable drive has a "write protect" switch, it must be set to the "unlock" position. Plug the removable drive into the USB-A port on the back of the monitor. To export data:

1. Press the **[Export Data]** touch key. The display shows the data types available for export.
2. Press the desired data type, then press **[Begin Export]**.

3. Export begins. If you press **[Return to Home Menu]** the export process will continue to run in the background. The status of the export can be viewed at any time by selecting **[Export]** from the Menu system.
4. During Export, the USB Export icon displays on the screen below the BIS number. (See Section 3.3.7.2 "USB Export Icon.")
5. When the export status screen displays "100% complete," the drive may be removed from the back of the monitor. To stop Live Export, press **[Stop Export]** before removing the drive.

To exit while the export is still running, press **[HOME]**. To stop the export, press **[Stop Export]**.

Caution:
Do not remove drive while export is in progress.

3.5.12 BIS Smoothing Rate

To access the **BIS Smoothing Rate**:

1. Press **[MENU].**
2. Press **[Next].**

Figure 24 - Smoothing Rate

The BIS VISTA system offers three choices of smoothing rates over which the BIS value is averaged:

- 10 seconds: Provides increased responsiveness to state changes, such as induction or awakening. This is the default setting for Monitor Mode III.
- 15 seconds: This is the default setting for Monitor Modes I and IV.
- 30 seconds: Provides a smoother trend with decreased variability and sensitivity to artifact. This is the default setting for Monitor Mode II.

To change the Smoothing Rate, press the **[BIS Smoothing Rate]** touch key. The current Smoothing Rate displays in green letters. Press the key until the desired rate displays in green. Press **[HOME]** to exit.

To permanently save this change, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

3.5.13 Print (Snapshot)

Snapshot and Review data may be printed from the BIS VISTA monitor. To print Review data, see section 3.6 "Reviewing Stored Trend Data." To print Snapshot data, use the **Print** menu selection. To access **Print**:

1. Press **[MENU].**
2. Press **[Next].**

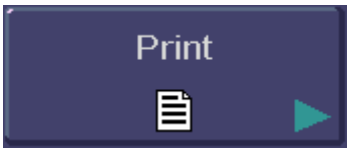


Figure 25 - "Print" Touch Key

This **Print** option allows the user to create a PDF file of the most recent Snapshot data and send it to a removable drive on the USB-A port. The removable drive can then be used to transfer the data to a personal computer for viewing or printing.

To "Print" Snapshot (send a printable file to a removable drive):

1. Attach the removable drive to the USB-A port.
2. Press **[MENU]**, then **[Next]** to get to the second menu.
3. Press **[Print]**, then press **[Snapshot]**.
4. A Print icon appears below the BIS number while the data transfer is in process. (See Section 3.3.7.3 "Print Icon.")
5. When the message "PDF creation completed" appears (or the Print icon disappears from the screen), the drive may be removed from the back of the monitor.

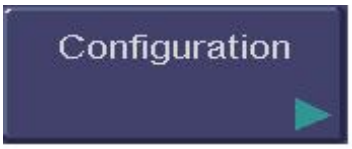
Each PDF file contains up to 4 pages; each page contains 30 seconds of data. The file name begins with "EEG" and is followed by: the case ID number, the date of the earliest stored data for the case, and the page range. For example, the file name EEG_AH5F_20070118_pgs1-4.pdf is a file containing 4 pages of snapshot data from case # AH5F, and the earliest data available for that case is from January 18, 2007.

Files for a particular case are stored in a folder. The folder name starts with 'EEG' followed by the case ID number and the two-digit day and month, four-digit year, and two-digit hour, minute and second that the printing was started. For example, the folder EEG_AH5F – 18012007112722 includes all of the files relating to case ID #AH5F, and the data for that case was printed on January 18, 2007 at 11:27:22.

3.5.14 Configuration Information

To access **Configuration Information**:

1. Press **[MENU].**
2. Press **[Next].**



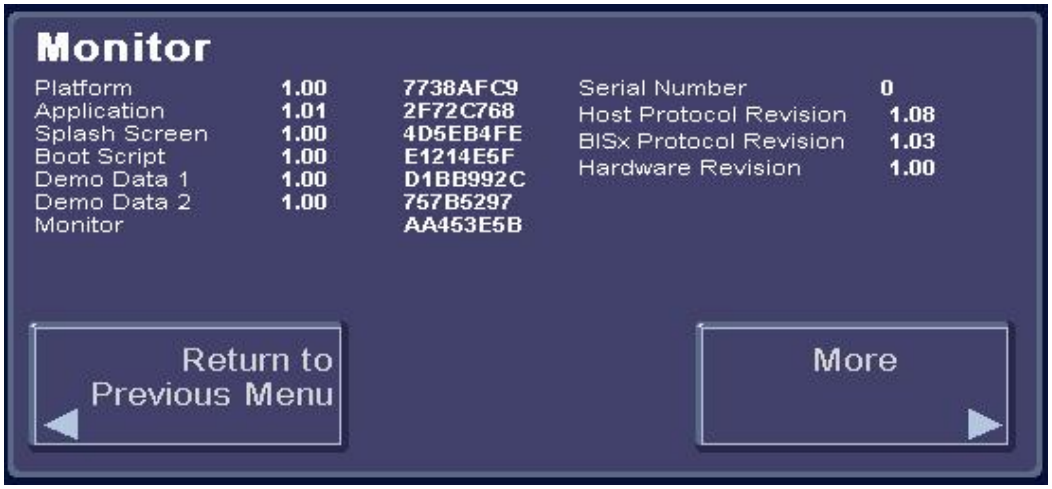


Figure 26 - Configuration Information

This option displays the current Monitor Mode and its settings, including:

- **Monitor:** Hardware and software revisions and the monitor serial number.
- **BISx:** Serial number, revisions and checksum.
- **Sensor:** Lot code, serial number and sensor type.
- **Languages**: Language revision numbers.

3.5.15 EEG Channels

To access **EEG Channels**:

1. Press **[MENU].**
2. Press **[Next]** to get to the next menu**.**
3. Press **[Next]** to get to the third menu.

Figure 27 - EEG Channels

The BIS VISTA monitor has the ability to display one or two channels of filtered EEG. To change the EEG display press the **[EEG]** touch key until the desired number of channels (1 or 2) is displayed in green. Press **[HOME]** to exit.

3.5.16 Date and Time

To access **Date and Time**:

1. Press **[MENU].**
2. Press **[Next]** to get to the next menu**.**
3. Press **[Next]** to get to the third menu.

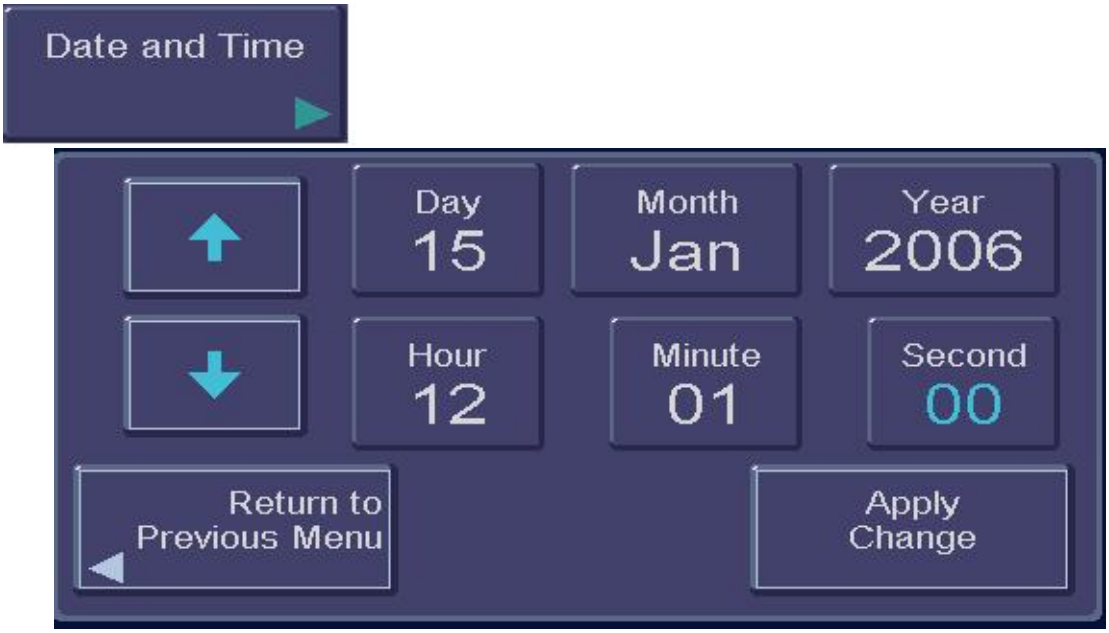


Figure 28 - Date and Time

To set the current date and time:

1. Press **[Date and Time].** A new screen displays the current date and time. "Day" is displayed in blue letters.
2. Use the up and down arrows to set the day of the month.
3. Press **[Month].** "Month" is displayed in blue letters.
4. Use the up and down arrows to set the month.
5. Repeat this process for the "Year," "Hour," "Minute" and "Second" displays.
6. Press **[Apply change]**.
7. When you have finished, you may press **[Return to Previous Menu]** or press **[HOME]** to return to the main screen.

Notes:

The time/date is initially set for the Eastern Standard or Eastern Daylight Time zone (USA). It will be necessary for you to change the time twice per year using the Time/Date feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

When time is set to an earlier hour, the following message appears on the screen: "Processing the requested change will result in loss of all data collected since [*date and time.*] Press 'Return to Previous Menu' to return to Date and Time Menu with no changes. Press 'Apply change' to apply the requested change".

Date and time cannot be changed while a case is in progress.

3.5.17 Language

To access **Language**:

1. Press **[MENU].**
2. Press **[Next]** to get to the next menu**.**
3. Press **[Next]** to get to the third menu.

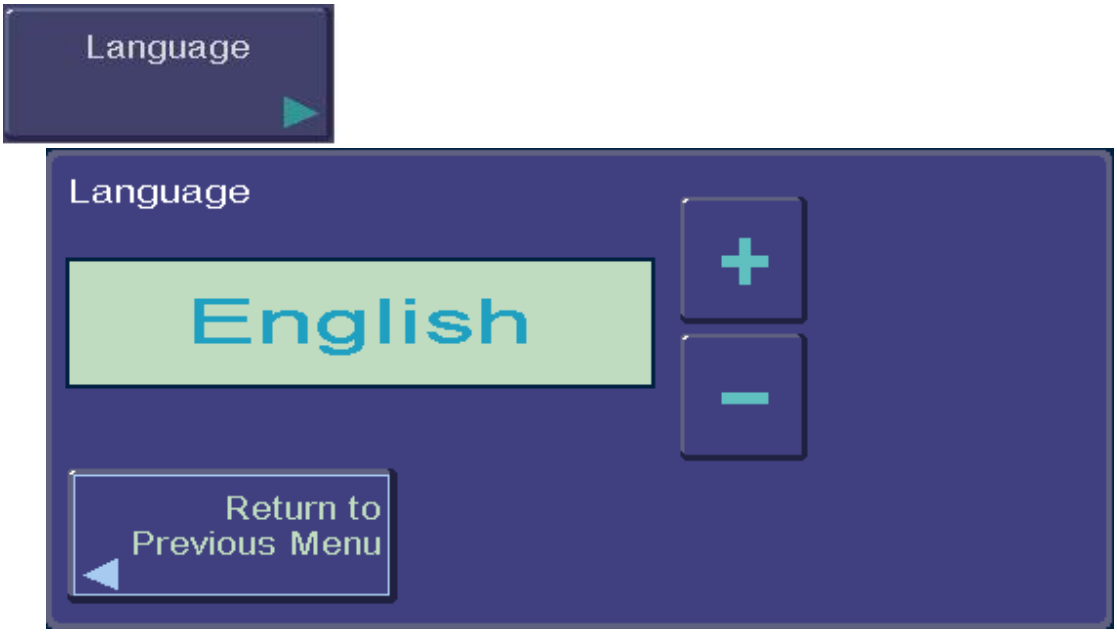


Figure 29 - Language Menu

The BIS VISTA monitor is designed to support multiple languages. If the screen does not display the desired language, follow these steps:

To change the language:

1. Press **[Language]**. The current language is displayed.
2. Use the **[+]** or **[-]** keys to scroll through the list of languages until the desired language appears. All screens will now display in the selected language.
3. Press **[HOME]** to return to the main screen.

3.5.18 Filters

To access **Filters**:

1. Press **[MENU].**
2. Press **[Next]** to get to the next menu**.**
3. Press **[Next]** to get to the third menu.

Figure 30 - Filters

The BIS VISTA system uses filters to screen out undesirable interference from the raw EEG signal display. The Notch filter includes filters for both 50 and 60 Hz. Filters ON or OFF does not affect processing of the Trend variables (i.e., BIS, EMG, and SR). Viewing the EEG signal without filters may aid in troubleshooting signal problems. If you prefer to observe the raw EEG without the filters, they may be turned off.

To turn the Filters off, press **[Filters]**.

- When the key shows a green box, the filters are ON.
- When the key shows a red box with an 'X', the filters are OFF.

This change is not saved with the Save Settings option. Filters will default to ON.

3.5.19 Impedance Checking

To access **Impedance Checking**:

1. Press **[MENU].**
2. Press **[Next]** to get to the next menu**.**
3. Press **[Next]** to get to the third menu.

Figure 31 - Impedance Checking ON/OFF

The BIS VISTA system continually checks impedance levels during a procedure by generating a 128 Hz test signal. Occasionally this signal may interfere with other equipment. If this becomes a problem, you may turn off the continuous impedance checking. Impedance levels will still be tested at startup, but once they pass, they will not be tested again until a new case is begun.

To turn continuous impedance checking off, press **[Impedance Checking]**. The key display will change from a green box to a red box with an 'X'. Press **[HOME]** to return to the main screen. The message, "Impedance Checking Off" will display on the screen during processing.

Note:

Turning off continuous impedance checking will not be saved by the "Save Settings" feature. The next time the monitor is started up or a new sensor is connected, the monitor will re-enable continuous impedance checking.

3.5.20 Maintenance Menu

The Maintenance Menu includes maintenance functions to test, update and restore settings to the monitor and BISx.

To display the Maintenance Menu:

1. Press **[MENU]** to access the menu options.
2. Press **[Next]** to proceed to the next menu.
3. Press **[Next]** again to proceed to the third menu.
4. Press **[Maintenance Menu]**. The Maintenance Menu appears.

Use of the Maintenance Menu is covered in Section 7, "Diagnostics and Troubleshooting."

3.5.21 Demo Case

To access **Demo Case:**

1. Press **[MENU].**
2. Press **[Next]** to go to the next menu**.**
3. Press **[Next]** to go to the third menu.
4. Press **[Demo Case]** to go to the Demo Case Menu.

This option allows the user to run a demonstration case. Press the **[Demo Case]** touch key to initiate a Demo Case. The Main Screen appears, with the heading, "Demo Case." To stop the demonstration, follow the instructions above to access the **[Demo Case]** touch key and press the touch key.

Note: The Demo Case function uses pre-stored simulated case data. It should not be used during patient monitoring at any time.

3.5.22 Diagnostic Menu

To display the Diagnostic Menu:

1. Press **[MENU]** to access the menu options.
2. Press **[Next]** to proceed to the next menu.
3. Press **[Next]** again to proceed to the third menu.
4. Press **[Diagnostic Menu]**. The Diagnostic Menu appears.

Contact Aspect Medical Systems, Inc. for instructions on use of the Diagnostic Menu. See back cover for contact information.

3.6 Reviewing and Printing Stored Trend Data

The BIS VISTA stores up to 72 hours of trend information. This information may be viewed using the monitor's "Review Mode." To enter the Review Mode, press the blue **[◀]** arrow key on the Main Screen display. The screen indicates that you are viewing Trend Review data.

The BIS numeric display for the current procedure will continue to be updated and parameter alarms will continue to be announced during Review Mode.

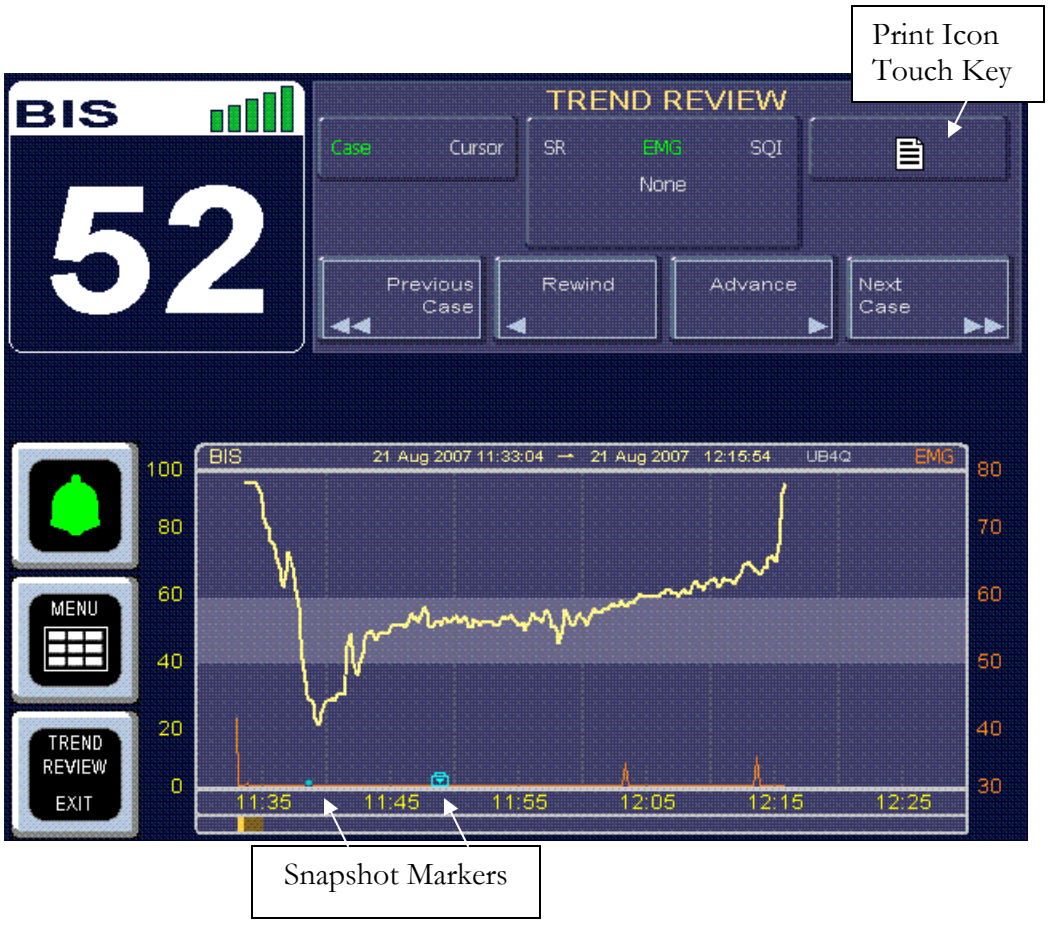


Figure 32 - Review Screen (Case Mode)

3.6.1 Review Mode Touch Keys

Press the **[Rewind]** touch key to move the display backward in time. To move to the beginning of the current case, press **[Case Start]**. If the case start is already displayed, you may press **[Previous Case Start]** to view the previous case. If the earliest case in memory is displayed, the key notifies the user that it has reached the "Beginning of BIS Trend Memory."

Press the **[Advance]** touch key to move forward in time. To move to the beginning of the next case, press **[Next Case Start]**. If the final data of the last case in memory is displayed, the key notifies the user that it has reached the "End of BIS Trend Memory."

The Review Mode screen displays a secondary trend plot if one has been selected in the menu system. To add or change the secondary trend, press the secondary variable touch key until the desired variable is displayed in green letters. Note that Burst/Minute will only display if a BIS Extend Sensor was used for the case.

Figure 33 - Review Screen (Cursor Mode)

Cursor Mode may be entered by pressing the **[Cursor]** touch key. Cursor mode allows the user to view BIS and secondary variable data for specific points on the trend graph. When the user touches the screen in the review display area, a box displays the time corresponding to the area touched, along with the BIS and secondary variable data. When the signal quality is not sufficient to calculate these values, they appear as asterisks.

In Cursor Mode, the "Rewind" and "Advance" keys are replaced by "Step Backward" and "Step Forward" keys. When these keys are pressed and released, they move the data displayed 10 seconds forward or backward in time. When they are pressed and held, they move the data displayed 60 seconds forward or backward in time.

To return to "Case Mode," press the **[Case]** touch key.

To return to the main display, press **[TREND REVIEW EXIT]**.

A **print icon touch key** is located in the upper right corner of the trend graph.

3.6.2 Printing Stored Data

Stored case data can be transferred via a removable drive to a personal computer for viewing or printing. (For information on printing Snapshot data, see section 3.5.13 "Print (Snapshot).")

To create a PDF of the currently displayed case data,

1. Attach a removable drive to the USB-A port.
2. Press the **print icon touch key** located in the upper right corner of the BIS Trend graph (see Figure 32). A set of printable PDF files is created for the currently displayed case and sent to the USB drive.
3. A Print icon appears below the BIS number while the data transfer is in process. (See Section 3.3.7.3 "Print Icon.")
4. When the message "PDF creation completed" appears (or the Print icon disappears from the screen), the drive may be removed from the back of the monitor.

Each PDF file contains up to 6 pages, with each page displaying 1 hour of trend data. The data include: the date, case ID number, case start and end time, the BIS trend graph, and a chart displaying the BIS value, SQI and EMG at one-minute time intervals. If the case was longer than 6 hours, an additional file is created in the same directory.

The name of each file begins with "BIS" and is followed by: the case ID number, the date of the earliest stored data for this case, and the page range. For example, the file name BIS_AH5F_20070118_pgs1-6.pdf is a file of BIS data from case # AH5F, which started on January 18, 2007 and consists of 6 pages of data.

Files for a particular case are stored in a folder. The folder name starts with 'BIS' followed by the case ID number and the two-digit day and month, four-digit year, and two-digit hour, minute and second that the PDF creation was started. For example, the folder BIS_AH5F – 18012007112722 includes all of the files relating to case ID #AH5F, and the data for that case was printed on January 18, 2007 at 11:27:22.

3.7 EEG Display

This display is a larger version of the EEG waveform display, shown in place of the BIS Trend Graph. Filtered EEG waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division (one channel display) or 50 µV per division (two channel display). EEG filters can be turned off in the menu system. When the EEG Display has been selected, a small version of the BIS Trend Graph is displayed in the top right corner of the screen.

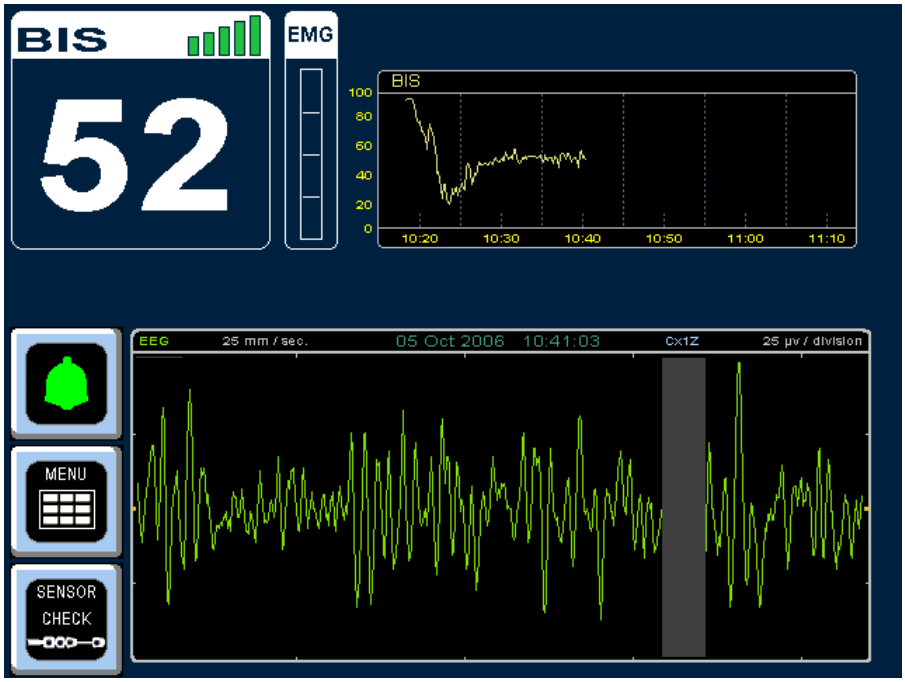


Figure 34 - EEG Display

3.8 Ending a Case

When the case has finished:

- Disconnect the patient sensor from the PIC by pressing the release button on the connector and then pulling the connectors apart. DO NOT pull apart by the cable wires.
- Remove BIS sensor from patient. Disposable sensors are single-use only.
- Be sure to leave the PIC with the monitor so that it is not inadvertently discarded.
- If this is the last procedure of the day, press and hold the ON/Standby button for two seconds before releasing to put the BIS VISTA monitor in Standby mode (a yellow light displays)
- Clean the BIS VISTA system between uses. See Section 5.1.

WARNING:
SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR

HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

Note: The BIS VISTA can remain plugged in to A/C power at all times.

3.9 Data Transfer

Three ports on the rear of the BIS VISTA monitor facilitate data transfer. The USB (Type A) port is used to export data to a removable drive and to update monitor and BISx software. See the following sections for use of the USB-A port:

- 3.5.11 "Export Data"
- 3.5.13, "Print (Snapshot)"
- 3.6.2 "Printing Stored Data"
- 6.1.3 "Software Update"

An RS-232 port is available to connect the monitor to a patient monitoring or recordkeeping system using an ASCII or Binary serial port protocol (see section 6.1.2 "Serial Protocol").

The USB (Type B) port is for manufacturer's use only.

WARNINGS:

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

3.10 How the BIS VISTA Monitoring System Works

A sensor placed on the patient's head transmits EEG signals to the BISx. The BISx filters the data, analyzes it for artifact and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.
A list of the processed variables and a description of each is provided in Appendix I. These data are displayed on the screen according to the preferences set by the user in the menu system.

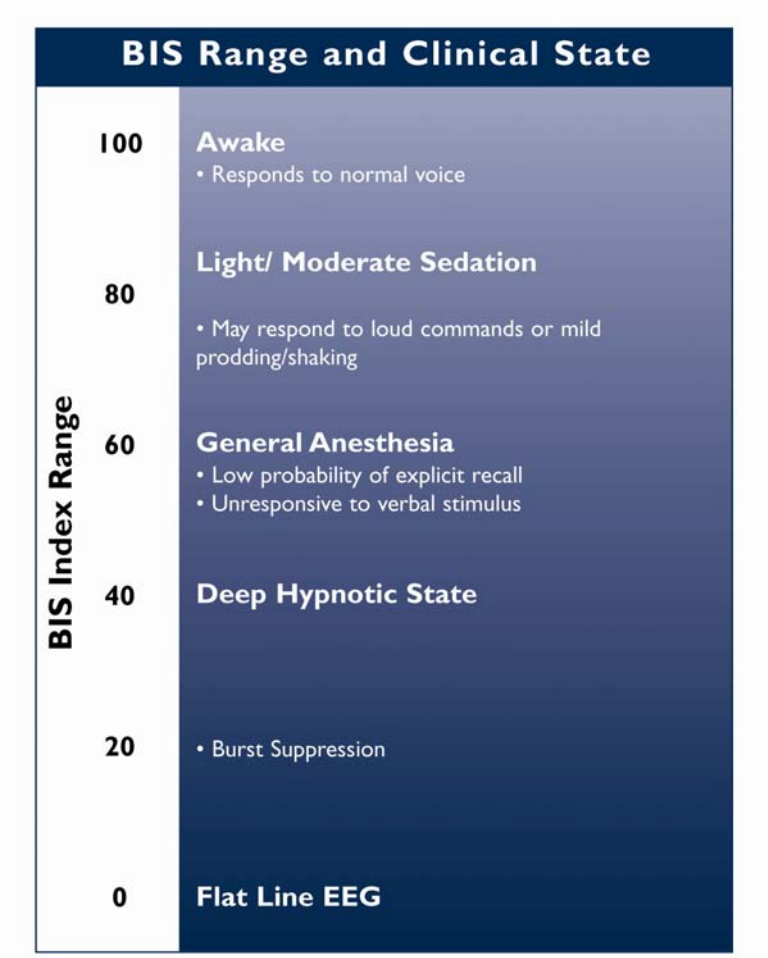


Figure 35 - BIS Range Guidelines

This chart reflects a general association between clinical state and BIS values. Ranges are based on results from a multi-center study of the BIS involving the administration of specific anesthetic agents. BIS values and ranges assume that the EEG is free of artifacts that can affect its performance. Titration of anesthetics to BIS range should be dependent upon the individual goals established for each patient. These goals and associated BIS ranges may vary over time and in the context of patient status and treatment plan.

3.10.1 Bispectral Index (BIS)

Range = 0 – 100

The Bispectral Index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. BIS was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain. BIS is displayed as a number in the upper left corner of the screen and is plotted over time on the BIS Trend Graph. When signal quality is too low to accurately calculate a BIS value, the BIS number is not displayed.

3.10.2 Artifact Detection

The BIS VISTA Monitoring System is designed to provide only highly reliable data. It is therefore programmed not to display data that has been corrupted by artifact. Artifact bars appear on the display whenever artifact is detected. In addition, a message appears whenever the signal cannot be processed due to excessive artifact.

3.10.3 System Self-Checks

The BIS VISTA monitor has several self-checking features to ensure that the system is operating properly. These include:

System Check
Initiated when the unit is started up, this test makes certain that system software and hardware components are functioning properly.

Equipment and Connection Checks
The system checks continuously to be sure that the BISx, the PIC, and patient sensors are operating properly and have not become disconnected.

DSC Self-Test
The DSC Self-Test tests the digital signal acquisition and conversion functions of the BISx. It is a thorough test of the entire signal processing chain inside the BISx. It does not test the PIC or sensor. The DSC Self-Test may be initiated in the Diagnostics Menu (see Section 7).

Sensor Integrity Check
This test begins each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

Impedance Check (Sensor Check)
Electrode impedance is tested when the BISx and PIC are connected and is monitored continuously unless the user has turned impedance checking off in the menu system.

Caution:
Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment, e.g., evoked potential monitors.

Ground Check
A test is performed immediately after every sensor check and at 10-minute intervals during monitoring to check the status of the patient ground connection. During the test, the EEG display shows a flat line and the message "GROUND CHECK" displays on the screen

Diagnostics
The BIS VISTA monitor provides diagnostic codes to assist the user in tracing the source of any problems that may occur. Codes are displayed above the Message Region only if the user has requested them in the Diagnostic Menu.

3.10.4 Monitor Data Memory

The monitor stores recorded trend data with time and date of acquisition. The duration of trend data stored is approximately 72 hours. Trend memory can be viewed on the screen in Review Mode.

When the memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the battery has been discharged and remains when the monitor is in the power off condition.

3.10.5 BISx Data Memory

The BISx stores processed EEG parameters, including the BIS value, with time and date of acquisition. History data stored in the BISx can be accessed by exporting it to a removable drive using the "Export Data" function. The duration of BISx data stored is approximately 1200 hours.

To view BISx history for a specific case, the user must first identify which BISx was in use during the case by looking up the BISx serial number in the Maintenance Menu's "BISx Connection History." The appropriate serial number BISx can then be connected to any monitor to export its History Data.

When the BISx memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the monitor battery has been discharged and remains when the monitor and BISx are powered off.

3.10.6 Battery Operation

In the event of a power failure or interruption of power during a procedure, the monitor automatically switches to back-up battery operation. A fully charged battery will provide approximately 45 minutes of operation. When the system is running on battery, a battery icon displays next to the BIS number, indicating the battery status. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color from green to orange. In addition, a "Battery Voltage Low" message blinks continuously in the Message area of the screen.

The Save Settings feature is disabled when the battery power is low. Battery recharge time is approximately 6 hours. The battery charges continually as long as the unit is plugged into A/C power.

Caution:

To completely remove power from the unit: put the monitor in Standby mode, disconnect power cord from the power receptacle of the monitor, then remove the battery from the monitor.

NOTE: The BIS VISTA monitor may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. (Refer to Section 6.4 "Using the Reset Button.")

4 QUICK REFERENCE GUIDE

This "Quick Reference Guide" is intended only as an operating checklist for users already familiar with the BIS VISTA monitor. Do not proceed unless you have read the "Important Safety Precautions" (Section 1 of this manual).

BASIC OPERATION
If the BIS VISTA system has already been installed, but has been put into Standby mode (after a previous surgery, for example), proceed as follows:

1. Verify that all power and other cables are connected properly.

    - The BISx's long cable to the BISx port on the monitor.
    - The Patient Interface Cable to the BISx unit.

2. Press the button in the right corner of the monitor to turn the monitor and BISx on. The button light will turn from yellow to green. The system will initiate a self-test to ensure that all equipment is operating properly.

3. Prepare sensor site and place BIS sensor on the patient in accordance with manufacturer's instructions.

4. Using the attachment clip, secure the BISx to a convenient location near the patient's head.

5. Insert the BIS sensor tab into the PIC connector until fully engaged.

You are now ready to begin monitoring. For detailed operating instructions and software configuration, read Sections 2 and 3. Current settings may be viewed at any time by viewing the appropriate menu.

5 PREVENTIVE MAINTENANCE, CARE AND CLEANING

INTRODUCTION

This section describes:

- Care and cleaning procedures
- Routine maintenance
- Technical documentation
- Instrument Identification.

5.1 Care and Cleaning

WARNING:
UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

Cleaning the Monitor and BISx
Clean any spillage of blood or solutions on either the monitor or BISx as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISx performance.

Disinfecting the Monitor and BISx
Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol® Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes).

After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the BISx and PIC connector ends with alcohol and allow to dry completely.

WARNING:
WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA) AS HAZARDOUS GASES MAY RESULT.

Caution:

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

Cleaning the Monitor Display

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

5.2 Maintenance

The BIS VISTA monitor is designed so that no periodic adjustment or calibration is required. Suggested routine maintenance includes: periodic checking of cable integrity, system checkout, checking the battery, and checking leakage current. Instructions on replacing the battery and power supply are included in this section should replacement be necessary. In the event that the touch screen needs calibration, follow the instructions in Section 6.1.5.

Caution:

Service or repairs must be performed only by qualified biomedical technicians.

5.2.1 Replace the PIC (Patient Interface Cable)

The Patient Interface Cable (also known as the PIC cable) is considered a consumable part of the system and is expected to wear out due to normal usage. The internal wires and/or connector contacts may fail with fatigue over time or become contaminated with foreign material. This is an expected occurrence, as it is with any equipment that utilizes lead wires or patient connection cables. Therefore, it is recommended that the PIC cable be tested on a periodic basis (see section 5.2.3 "System Checkout") and replaced if it has been in service for more than two years.

The PIC cable date of manufacture is printed on each cable and is located on a white label wrapped around the PIC cable. The manufacturing date code is identified in one of the following methods:

- "PIC+ mmddyy" (month, day, year)
- "PIC+ mm/dd/yy" (month, day, year)
- "nnnnnnwwyy" (where ww is week and yy is year)

Replacing the PIC cable is an important routine maintenance action which will improve the reliability of the BIS monitoring system.

5.2.2 Checking Cable Integrity

The BIS VISTA System should be inspected periodically to ensure that all cables are in working order, with no cuts in electrical insulation. Cables can be flexed during the system checkout (See Section 5.2.3) to ensure there are no loose wires.

5.2.3 System Checkout

A system checkout should be done periodically to verify that all system components are in working order. Follow the instructions below for System Checkout.

1. Disconnect the BISx from the monitor.

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.
   - Verify that the light to the right of the ON/Standby button is yellow.

3. Start up monitor by pressing the ON/Standby button (lower right corner).
   - Verify that the light to the right of the ON/Standby button is green.
   - Verify all self-tests complete successfully.
   - Verify next screen says "Connect BISx."

4. Connect BISx with PIC to monitor.
   - Verify screen says, "BISx Initialization Complete."
   - Verify that screen says, "Connect sensor or cable."

5. Connect PIC and sensor.
   - Verify SENSOR CHECK begins.

6. Disconnect power cord from monitor.
   - Verify 'OPERATING ON BATTERY BACKUP' is displayed.
   - Verify battery icon displays below BIS number.

7. Reconnect power cord.
   - Verify battery icon is not displayed below BIS banner.
   - Verify 'OPERATING ON BATTERY BACKUP is not displayed.

8. End of checkout.

5.2.4 Checking the Battery

Check the battery periodically by operating a BIS VISTA monitor that has been disconnected from the wall socket and that has been charging the battery for at least 6 hours. If the monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

WARNING:
ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

LEAKAGE CURRENT MUST BE CHECKED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN WHENEVER INSTRUMENT CASE IS OPENED.

Caution:
Check the battery periodically by operating a BIS VISTA monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage, charge the battery for 6 hours to assure full capacity. If the BIS VISTA monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VISTA monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

NOTE: The BIS VISTA monitor may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. (Refer to Section 6.4 "Using the Reset Button.")

5.2.5 Replacing the Battery

To replace the battery, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the monitor.
2. Lay monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. Note the position of the battery cable.
4. Squeeze the battery connector latch to disengage it from the back of the monitor and remove the old battery.
5. Lay the new battery in the recess with the wires at the top, and plug in the connector.
6. Replace the cover and four screws (hand-tighten only) and reconnect the A/C power cord.

5.2.6 Replacing the Power Supply

Figure 36 - Replacing the Power Supply

WARNING:
POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VISTA POWER SUPPLY.

To replace the power supply, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the BIS VISTA monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the battery and the power supply connectors.
5. Remove screws from the power supply bracket and remove the old power supply.
6. Insert new power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
7. Reconnect the power supply.
8. Reconnect the battery.
9. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

5.2.7 Checking Leakage Current

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each BIS VISTA monitor is carefully checked at the factory to verify that leakage current meets the UL60601-1 and IEC60601-1-1 safety standards.

The BIS VISTA monitor should be checked routinely for leakage current at least once a year.
Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and after every time the monitor case has been opened.

Keep in mind that liquids such as saline and Ringer's as well as blood are all excellent conductors of electricity. Avoid touching any part of the system with wet hands. Always work with clean, dry hands.

WARNING:
ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS. WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST BEFORE FURTHER USE.

The BIS VISTA Monitoring unit **does not** contain a ***Protective Earth Stud (GND Stud)***. Since the exposed metal parts on the rear of the BIS VISTA Monitor (Communication serial port and USB ports) are separated from live parts by double insulation, a ground continuity test does not apply to these parts. The components of the BIS VISTA Monitor that are connected to protective earth are contained within its enclosure and are not accessible to the user of the equipment. However, as stated in the operating manual, an enclosure leakage current test should be performed on the exposed metal parts and should be checked periodically to ensure that the integrity of the equipment's insulation system is maintained. The leakage current test should include measurement of ground wire leakage, enclosure leakage, and patient leakage.

Ground wire leakage typically can be performed automatically by connecting the A/C power cord of the BIS VISTA Monitor into a safety tester. The enclosure leakage may be measured by any safety test equipment that is capable of connecting to isolated conductive parts and measuring the current from those parts to earth. The patient connection terminals of many safety testers can be used for this purpose. The patient leakage current can be measured by connecting the patient connection terminals of a safety tester to the patient input connection (the PIC) of the BISx.

The BIS VISTA Monitor has been certified by Underwriters Laboratories to comply with IEC60601-1, as indicated on the labeling on the rear of the monitor.

5.3 Technical Documentation

The BIS VISTA Monitoring System is designed and manufactured using state-of-the-art components and manufacturing processes. Field repair or customer repairs are therefore limited by design to replacement of major component assemblies such as: the Patient Interface Cable (PIC), BISx, the BIS VISTA Monitor itself, the battery, power supply and pole clamp. Periodic software updates are possible via the USB-A port.

This BIS VISTA Operating Manual contains the maintenance and diagnostic troubleshooting information necessary for customer qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal components of the BIS VISTA monitor or the BISx.

5.4 Instrument Identification

BIS VISTA Monitor
Monitor identification information is permanently marked on the rear panel. This information includes instrument model and serial numbers, power ratings, cautions, and the Aspect Medical Systems' shipping address.

BISx
The BISx identification information is permanently marked on the rear panel of the BISx. The information includes instrument model and serial numbers, patent numbers, cautions, and the Aspect Medical Systems' shipping address.

Software Revision Numbers
Software revision numbers are displayed in the Configuration Information screen.

6 DIAGNOSTICS AND TROUBLESHOOTING

INTRODUCTION

This section discusses:

- The Maintenance Menu
- The Diagnostic Menu
- BIS VISTA monitor messages and appropriate operator actions
- Resetting the system
- What to do if the BIS VISTA system requires service.

6.1 Maintenance Menu

The maintenance menu contains functions to test and maintain the BIS VISTA system, including the BISx, PIC, and sensors.
To display the Maintenance Menu:

1. Press **[MENU]** to access the menu options.
2. Press **[NEXT]** to proceed to the next menu.
3. Press **[NEXT]** to proceed to the third menu.
4. Press **[Maintenance Menu]**. The Maintenance Menu appears.

6.1.1 Display BISx Connection History

This option displays information on each BISx that has been connected to a specific monitor. The connection time, BISx serial number and BISx software revisions are displayed.

6.1.2 Serial Protocol

Data may be transmitted from the serial port in two formats, ASCII (Legacy) and Binary (Legacy Binary or VISTA Binary). Legacy versions are provided for customers whose equipment was set up with older BIS monitor software (A-2000 serial protocol revision 1.08 or less). When using the ASCII protocol, new features can be enabled by a serial port command.

To change the serial protocol:

1. Press **[Serial Protocol].**
2. Press the desired protocol. The protocol selected displays in yellow, indicating that it is the active protocol until the next time the system is re-started.
3. To permanently save this change, press **[Save Setting]**. Note that this change will apply to all modes. The protocol selected now displays in white.
4. Press **[HOME]** to exit.

Data is continuously streamed from the RS-232 port in the specified format and can be acquired by attaching a serial line to the port in the back of the monitor. Contact Aspect Medical Systems for the BIS Monitor Serial Port Technical Specification. (See back cover for contact information.)

6.1.3 Software Update

The BIS VISTA system software may be updated by attaching a removable drive containing the update to the USB port on the rear of the monitor. Follow these steps to perform the update:

Note:

The monitor must be connected to A/C power to perform the update.

Caution:

Do not disconnect the BISx during the software update.

1. Insert the USB drive containing the software update into the USB port (Type A) at the rear of the monitor.
2. Press **[MENU]**, then **[Next]**, then **[Next]** again to get to the third menu.
3. Press **[Maintenance]** to reach the Maintenance Menu.
4. Press **[Software Update]**. As soon as the updating device is detected, a list of the available updates appears on the screen.
5. Press **[Continue]** to initiate the update. (To skip the update, Press **[Cancel]**. The monitor will operate with the current software.) The update begins. Do NOT remove the USB drive during the updating process.
6. If the message, "Connect BISx to monitor" appears on the screen, a BISx software update is available. Connect the BISx to continue with the update, or press **[Cancel]** to skip the update.
7. When the update is complete, the message "Software Update Complete" appears. Remove the USB drive and press **[RESET]**. The monitor and BISx will reset, and you can then resume normal operation.

6.1.4 Restore Default Settings for All Modes

This option resets all settings (for all Monitor Modes: I, II, III, and IV) to the original settings. To permanently save this change, press the **[View/Save Settings]** touch key in the menu system, then press **[Save Active]**.

6.1.5 Calibrate Touch Screen

The Touch Screen is calibrated at the factory and does not need to be re-calibrated on a regular basis. However, if necessary, the touch screen may be calibrated by selecting **[Calibrate Touch Screen]** from the menu system. Follow the on-screen instructions.

6.2 Diagnostic Menu

The Diagnostic Menu contains functions to test and maintain the BIS VISTA system. If you should experience a problem with the BIS VISTA system, Aspect's Technical Service Department will direct you in using these functions. To contact Aspect, please refer to the back cover of this manual.

6.2.1 Diagnostic Codes

Figure 37 - Diagnostic Codes ON/OFF

If you are experiencing problems with the BIS VISTA system, Aspect's Technical Service may direct you to turn the Diagnostic Codes ON so that numeric diagnostic values will be displayed in the Message Region of the screen. To do so, press the **[Diagnostic Codes]** touch key until a green box appears. Press **[HOME]** to exit.

6.2.2 DSC Self Test

The DSC Self Test tests the digital signal acquisition and conversion functions of the BISx. It is a thorough test of the entire signal processing chain. The DSC test reports PASS/FAIL status. When the BISx passes the test, noise, high-pass blocked, high-pass normal and gain values are also reported. If any of the self-tests fail, notify your Biomedical Engineering Department or your Aspect Medical Systems service representative. See Section 6.5 "What to do if the BIS VISTA System Requires Service."

6.3 BIS VISTA System Messages and Corrective Actions

When an alarm is triggered, a message appears in the Message Region of the screen. Possible messages and the recommended operator actions are listed below. It is a good idea to write down the exact status message number when it occurs and have that information available if you should need service. See Section 6.5 "What to do if the BIS VISTA Monitoring System Requires Service."

BIS VISTA Messages and Operator Actions

Status Messages:	Possible Causes:	Corrective Actions:
Connect BISx	1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor.	1. Connect BISx. Verify all cable connections. 2. Inspect/repair cable at connector end. 3. Replace the BISx. 4. Replace monitor.
Press electrode(s) *x, y* **Temporarily unable to measure electrode(s) *x, y*** **[13]**	1. Sensor is not fully in contact with patient's skin. 2. Incorrect sensor application. 3. Defective PIC. 4. Defective BISx.	1. Press electrode indicated on the screen. 2. Read Instructions on sensor package to ensure correct sensor placement. 3. Replace the PIC. 4. Replace BISx.
Sensor Disconnected/ Connect sensor or cable **[14]**	1. Disconnected sensor. 2. Poor or contaminated connection between sensor and PIC. 3. Disconnected PIC. 4. Defective PIC. 5. Defective BISx.	1. Connect the sensor. 2. Connect/clean connection between sensor and PIC. 3. Connect the PIC. 4. Replace the PIC. 5. Replace the BISx.

Status Messages:	Possible Causes:	Corrective Actions:
Last Sensor Check Failed / Restart sensor check or reconnect sensor [16]	1. At least one element of sensor has too high impedance, and EXIT pressed (before sensor check completes). 2. Incorrect sensor application. 3. Poor sensor connection. 4. Defective PIC. 5. Defective BISx.	1. Verify Sensor Check passes. 2. Read Instructions on sensor package and re-apply sensor. 3. Check sensor connection. 4. Replace the PIC. 5. Replace the BISx.
Excessive Artifact Detected in Signal [27]	The Signal Quality is less than half of the level desirable for optimal monitoring conditions. 1. Artifact, such as those generated by motion or eyeblinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note:** This message may occur as the results of artifact (non-EEG signal) such as those generated from motion (patient movement or eye blinks) or the presence of electro-cautery, warming blankets, or other devices	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx.

Status Messages:	Possible Causes:	Corrective Actions:
Data unavailable due to poor signal quality [28]	The signal quality is too low to accurately calculate a BIS value. The BIS value and other trend variables that are adversely affected by artifact are not displayed 1. Artifact, such as those generated by motion or eye blinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note**: This message may occur as the results of artifact (non-EEG signal) such as those generated from motion (patient movement or eye blinks) or the presence of electro-cautery, warming blankets, or other devices.	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx.
BIS Out of Target Range **Low – [29]** **High – [30]**	The BIS has fallen outside the target range set by the user.	1. Check patient. 2. Take note of BIS at limit set by user.

Status Messages:	Possible Causes:	Corrective Actions:
Isoelectric EEG Detected **[31]**	No discernible EEG activity is detected for sixty-three seconds; SR=100. **Note:** This message notifies user of a flatline EEG. This is a normal condition when Sensor Simulator or Test Sensor is connected.	If unintended: 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self-test passes. 5. Verify PIC. Use Test Sensor or Sensor Simulator and Sensor Check.
Operating On Battery Backup **[33]**	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 45 minutes (when the battery is fully charged).	1. Restore the AC power. 2. Verify power cord. 3. Replace power supply.
Battery power low **[34]**	There are only a few minutes of battery life left.	Restore AC power to avoid automatic shutdown.
Replace with compatible sensor **[83]**	The sensor is not compatible with the monitor configuration.	Replace sensor.
Sensor Ground Fault **[92]** (negative) **[93]** (positive)	Problem is detected relating to sensor ground element.	1. Disconnect and examine sensor connection. Clean any contamination present. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.
Sensor Overcurrent **[94]**	Sensor is using too much current.	1. Disconnect and examine sensor connection. Clean any contamination. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.

Status Messages:	Possible Causes:	Corrective Actions:
No more Uses for this Sensor [95]	Sensor has been connected and disconnected too many times.	Replace the sensor.
Reinsert sensor firmly [96]	1. Poor or contaminated connection between sensor and PIC. 2. Defective PIC. 3. Defective BISx.	1. Connect/clean connection between sensor and PIC. 2. Replace the PIC. 3. Replace the BISx.
Sensor used for over 24 hours [109]	Sensor was attached to system for more than 24 hours.	Replace sensor.
Data export error [512]	(See Message 3000)	
Date and time not changed [513]	A case was in progress when the time/date was changed.	Change the date/time after the case has finished.
Trend memory error [516]	Trend memory is full or data has been corrupted.	Disconnect the BISx and restart monitor. Do not reconnect the BISx until directed.
Unrecoverable BISx error [517]	(See Message 1000)	
No data available [524]	1. No data has been written to the BISx/monitor. 2. Defective BISx. 3. Defective monitor.	1. Try again after a case has been run. 2. Replace BISx. 3. Replace monitor.
PDF creation halted: USB error [527]	1. Removable drive is not connected properly to USB(A) port. 2. Drive "write protect" is locked. 3. Drive is incompatible or defective. 4. Drive is full.	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive. Contact your Aspect Technical Service representative for a list of compatible drives. 4. Replace drive.

Status Messages:	Possible Causes:	Corrective Actions:
System error [533]	(See Message 2000)	
Snapshot corrupted [537]	(See Message 6000)	
System error [538]	(See Message 2000)	
Export halted: USB drive not detected [539]	1. Removable drive is not connected properly to USB(A) port. 2. Drive is incompatible or defective. 3. USB port is defective.	1. Check connection. 2. Replace drive. 3. Replace monitor.
Export halted: USB drive full [540]	1. Removable drive is not connected properly to USB(A) port. 2. Drive "write protect" is locked. 3. Drive is incompatible or defective. 4. Drive is full.	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive. Contact your Aspect Technical Service representative for a list of compatible drives. 4. Replace drive.
Export halted: BISx not detected [541]	1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor.	1. Connect BISx. Verify all cable connections. 2. Inspect/repair cable at connector end. 3. Replace the BISx. 4. Replace monitor.
Export halted: USB drive full [544]	(See Message 540)	
Export halted: USB drive not detected [545]	(See Message 539)	
Replace PIC. Possible PIC problem. [548]	1. Defective PIC. 2. Defective Sensor Simulator.	1. Test another PIC with Sensor Simulator. 2. If failure persists, replace simulator and retest.

Status Messages:	Possible Causes:	Corrective Actions:
Possible PIC problem. Check cable using Sensor Simulator [549]	Defective PIC	1. Test PIC using Sensor Simulator or Test Sensor. 2. Replace PIC.
Unrecoverable BISx Error / BISx initialization error [1000-1999]	1. Poor connection between BISx monitor cable and monitor 2. Defective BISx. 3. Defective monitor.	1. Follow on-screen instructions. If necessary, power OFF and unplug power cord to shut down monitor completely. Then plug in and re-start monitor. 2. Replace the BISx. 3. Replace the monitor.
System Error/ Unrecoverable Monitor Error [2000-2999] **Hardware Timer Error [2902]**	A system error has occurred. The monitor may stop operating. A system timer error has occurred.	1. Follow on-screen instructions (if any). 2. Turn the monitor off, then on again. 3. Reset monitor. 4. Replace monitor.
Data Export Error [3000-3999]	The data export was not successful. 1. Removable drive is not connected properly to USB(A) port. 2. Drive "write protect" is locked. 3. Drive is incompatible or defective. 4. Drive is full.	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive. Contact your Aspect Technical Service representative for a list of compatible drives. 4. Replace drive.
Unable to Update Software [4001- 4999]	1. Software has already been updated to the current revision. 2. A software error has occurred.	1. Check Revision. 2. Restart monitor. 3. Reset monitor. 4. Replace drive.
Trend Memory Error [5000-5999]	A memory error has occurred.	1. Restart monitor. 2. Reset monitor. 3. Replace monitor.

Status Messages:	Possible Causes:	Corrective Actions:
Snapshot Error [6000- 6999]	Operating system has noted that the snapshot process has not completed correctly.	1. Retry snapshot. 2. Restart monitor. 3. Reset monitor. 4. Replace monitor.

6.4 Using the Reset button

The Reset button is located on the back panel of the monitor. If necessary, the software can be reset by accessing this button with a ballpoint pen, paper clip or other similar tool.

6.5 What to do if the BIS VISTA Monitoring System Requires Service

Contact your local distributor to determine where servicing will occur. Aspect's Technical Service Department will assist you in isolating the problem to a specific component. Have the equipment available when you call so that you can supply the appropriate serial numbers and a detailed description of the problem. If it becomes necessary to return a unit directly to Aspect Medical Systems, follow the procedure below:

- Contact Aspect's Technical Service Department to obtain a Returned Materials Authorization (RMA) number. (The Technical Service phone number is printed on the back cover of this manual.) The RMA number must appear on the outside of the shipping container.

- Use the original shipping container, if available, or equivalent packaging to protect the product. Seal the package with plastic shipping tape rather than masking tape. Mark shipping or storage container FRAGILE.

- If the repair or replacement is covered by the warranty, Aspect will bear the costs of shipping the repaired or replacement product back to the user. All other shipping costs shall be paid by the user.

7 APPENDIX I: MENUS, PROCESSED VARIABLES AND GLOSSARY

7.1 Menu Map

Figure 38 - BIS VISTA Menu Map

7.2 Menu Listing

Menu Item		Options	Default Value
Target Range	Target Range Active Target Alarm Target Range Format Target Range High (upper limit) Target Range Low (lower limit)	ON / OFF ON / OFF Band or Lines 5 – 100 0 – 95	OFF ON Band 100 (None) 0 (None)
Secondary Variable		None, Suppression Ratio, EMG, Signal Quality **BIS Extend:** Bursts/Minute	EMG
Chart Data	Charting Interval		15 minutes*
Alarm Volume		1-5	1
BIS/EEG Display Type		BIS or EEG	BIS
View/Save Settings		Save Active Restore Saved Restore Default	
Help			
Snapshot			
Display SR		ON / OFF	OFF*
Monitor Mode		I, II, III or IV	I
Export Data	Live Data History Data BISx Connection History Monitor Error Log Sensor Data Snapshot		
BIS Smoothing Rate		10, 15 or 30	15*
Print	Snapshot		

Menu Item		Options	Default Value
Configuration	**Monitor:** Serial number Software: Application Revision Application Checksum Platform Revision Host Protocol Revision BISx Protocol Revision Hardware Revision **BISx:** Serial Number Software Revision Software Checksum FPGA Revision SIC Revision Hardware Revision Protocol Revision **Sensor:** Lot Code: Serial Number Sensor Type		
EEG Channels		1 or 2	1
Date and Time			
Language		English French German Italian Spanish Portuguese Polish Swedish Dutch	English
Filters		ON / OFF	ON
Impedance Checking		ON / OFF	ON
Maintenance	 Display BISx Connection History Serial Protocol Software Update Restore Default Settings for All Modes Calibrate Touch Screen	 ASCII Legacy Binary VISTA Binary	 ASCII

Menu Item		Options	Default Value
Demo Case		ON / OFF	OFF
Diagnostics	Diagnostic Codes DSC Self Test Monitor Error Log Clear Trend Data	ON / OFF	OFF

***These values are for Monitor Mode I. For other modes, consult Figure 22, "Monitor Mode Settings.**

7.3 Processed EEG Variables

Variable Name	Description	Range
Bispectral Index (BIS)	The output from a multivariate discriminate analysis that quantifies the overall bispectral properties (frequency, power, and phase) throughout the entire frequency range.	0 – 100
Signal Quality Indicator (SQI)	A measure of the signal quality for the EEG channel source(s) that is calculated based on impedance data, artifact, and other variables. Not affected by Suppression Ratio.	0 – 100 20 points per bar
EMG	The absolute power in the 70-110 Hz range. The power value is reported in dB with respect to $0.0001\mu V^2$. All the artifact detection is turned off for this variable.	30 – 80 dB Trend 30 – 55 dB Bar Graph
Suppression Ratio (SR)	The percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed.	0 – 100 %
Burst Count	The number of EEG bursts per minute, where a "burst" is defined as a short period of EEG activity preceded and followed by periods of inactivity (suppression).	0 – 20

7.4 Glossary

Amplitude
The maximum absolute value reached by a voltage or current waveform.

Artifact
An electrical waveform with characteristics that arise from sources other than the heart or brain.

Bispectral Index
The Bispectral Index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. BIS was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain.

BIS Sensor
A single patient use, disposable, pre-gelled 4 electrode array that is applied directly to the patient's forehead to record electrophysiological signals. The BIS sensor tab contains an electric smart card memory device that stores configuration and identification information.

BISx
The BISx is the small unit that attaches to the BIS VISTA monitor via its own monitor cable, and attaches to a BIS sensor via the Patient Interface Cable (PIC). It acquires and processes EEG information and sends it to the monitor for display.

Burst Count
The number of EEG bursts per minute, where a "burst" is defined as a short period of EEG activity preceded and followed by periods of inactivity (suppression). The duration of bursts and suppressions can vary from less than half a second to several seconds.

Electroencephalogram (EEG)
A visual representation of the rhythmic fluctuations of electric potential between parts of the brain (brain waves).

Electromyelogram (EMG)
A visual representation of the power (in decibels) in the frequency range 70 – 110 Hz. This frequency range contains power from muscle activity as well as power from other high-frequency artifacts.

Epoch
A short interval of arbitrarily defined length.

Impedance
The measure of the quality of the sensor electrodes' contact. Impedance is the amount of resistance that the electrical current encounters. Impedance is continuously monitored to ensure adequate signal quality.

Isoelectric EEG
Electrocerebral silence (flat EEG) or no significant electrical activity in the brain. Specifically, periods >240 msecs during which the electroencephalographic voltage did not exceed 5 [mu]V). A long period (>1 minute) of isoelectric EEG leads to suppression, indicated by a high suppression ratio and the message "Isoelectric EEG."

Montage
Standardized electrode locations.

Patient Interface Cable (PIC)
The cable that connects the BIS sensor to the BISx.

Signal Quality Indicator (SQI)
A measure of the signal quality for the EEG channel source that is calculated based on impedance data, artifact, and other variables.

Smoothing Rate
The rate over which the BIS value is averaged.

Suppression Ratio
A calculated parameter that indicates when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state (isoelectric). When SR equals 100, it means that during 100% of the last 63 second time period, no significant amount of electrical activity was detected.

8 APPENDIX II: SPECIFICATIONS, WARRANTY AND SOFTWARE LICENSE AGREEMENT

8.1 Specifications

This section lists specifications for the BIS VISTA Monitoring System.

General Specifications:

- Product Description: BIS (Bispectral Index) monitoring system for display of processed data and real-time EEG waveforms
- Monitor Weight: 3.5 lbs (1.6 kg)
- Monitor Dimensions: 7.5 in wide x 8 in high x 5 in deep (19 cm x 20.3 cm x 12.7 cm)
- Display Size: 4 in high x 5.25 in wide (10 cm x 13 cm)
- Digital Output: USB ports A, B, RS232 serial port
- Power Requirements: 100-240 VAC, 50-60 Hz, 0.7 ampere max.
- Electrical Safety: Conforms to: UL 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1
- Battery Backup: 45 minutes at full operation
Recharge Time: 6 hours
- Software Updates: User-via USB port (Type A)

EEG Specifications:

- Epoch Duration: 2 seconds
- Artifact Rejection: Automatic
- Input Amplifier Range +/- 1 mV
- EEG Scales: One channel display: 25 μV/div (+/- 50 μV full scale) Two channel display: 50 μV/div (+/- 50 μV per waveform)
- EEG Sweep Speed: 25 mm/sec
- Computed Parameters: Bispectral Index, Suppression Ratio, EMG, Signal Quality Indicator, and Burst Count
- User-defined Displays: Trend and real-time EEG waveforms
- Update Rate: 1 second for BIS number, 10 seconds for Trend
- Event Markers: User selected
- Alarms: Auditory and visual, user adjustable limits
- Filters: ON (2 – 70 Hz with notch) or OFF (.25 – 100 Hz)
- Mode: Sensor automatically selects mode.

BISx Specifications:

- BISx:
  - Weight: 10.0 oz (0.284 kg) including integral cable
  - Dimensions: 3.75 in diameter x 2.5 in thick (9.5 cm x 6.3 cm)
  - Cable Length: 9 ft (2.7 m) Integral BISx Cable; 4 ½ ft (1.4 m) from BISx to sensor connector
- Analog to Digital Converter: Noise-shaped sigma-delta
- Sampling Rate: 16,384 samples/second
- Resolution: 16 Bits at 256 samples/second
- Input Impedance: 50 Mohms typical
- Noise: < 0.3 μV RMS (2.0 μV peak-to-peak); 0.25 Hz to 50 Hz
- Common Mode Rejection: (Isolation mode) 110 dB at 50/60 Hz to earth ground
- Frequency/Bandwidth: 0.16 – 450 Hz

Type of Protection against Electric Shock of the System:

Class 1: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Degree of Protection against Electric Shock of the System:

Type BF: Equipment providing a degree of protection against electric shock regarding allowable leakage currents and reliability of the protective earth ground connection with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. The circuitry inside the BIS VISTA monitor is isolated from the mains in accordance with IEC 60601-1. Patient isolation is accomplished within the BISx.

Degree of Protection against effects of Cardiac Defibrillation:

The BIS VISTA system provides protection for the operator and patient during cardiac defibrillation. This protection is achieved via the isolation barrier within the BISx.

Degree of Protection against the Ingress of Water:

Monitor degree of protection rating: IPX2 (ingress of water vertically dripping).
BISx degree of protection rating: IPX4 (splash proof).

Mode of Operation of the System:

Continuous: Operation under normal load for a normal period without exceeding the specified limits of temperature.

Classification:

MEDICAL ELECTRONIC EQUIPMENT

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.® WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1.

8.2 Electromagnetic Compatibility Specifications

The BIS VISTA Monitoring System requires special precautions regarding Electromagnetic Compatibility (EMC). The BIS VISTA system must be installed and put into service according to the EMC guidance information provided in this section.

Portable and mobile radio frequency communications equipment can affect the operation of the BIS VISTA Monitoring System. Refer to the EMC guidance information and Cautions provided in this manual.

8.2.1 Accessories

The BIS VISTA Monitoring System complies with the requirements of IEC 60601-1-2:2001 when used with the accessories listed in Section 2 of the Operating Manual. In addition, the BIS VISTA system must be used only with the power cord provided.

When using a removable drive to load new versions of software into the BIS VISTA monitor, no cables or other accessories should be connected to the device. The BIS VISTA monitor should be connected to the mains through the appropriate power cord, and the removable drive should be plugged into the USB-A connector on the back of the monitor.

Caution:

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VISTA Monitoring System.

8.2.2 IEC 60601-1-2:2001 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for the BIS VISTA Monitoring System as per IEC 60601-1-2.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The BIS VISTA system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The BIS VISTA system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Caution:

The BIS VISTA system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VISTA Monitor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VISTA system is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines.	±2 kV for power supply lines. ±1 kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical hospital environment. If the user of the BIS VISTA system requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the BIS VISTA Monitor be powered by an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
NOTE: UT is the AC mains voltage prior to the application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BIS VISTA system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$, 80 MHz to 800 MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is

affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIS VISTA system is used exceeds the applicable RF compliance level above, the BIS VISTA system should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the BIS VISTA system

[b] Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BIS VISTA Monitor

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BIS VISTA system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIS VISTA system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

8.3 Warranty

Aspect warrants to the initial Purchaser that the BIS VISTA monitor and the BISx ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Aspect's obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Aspect reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Aspect directly (see contact information on the back cover of this manual). Aspect will authorize Purchaser to return the Warranted Product (or part thereof) to Aspect. Aspect shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Aspect's property. In the course of warranty service, Aspect may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Aspect reasonably determines that a repair or replacement is covered by the warranty, Aspect shall bear the costs of shipping the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a Product to Aspect in unsuitable packaging, any physical damage present in the Product on receipt by Aspect (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

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